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No. 84-1529

In the Supreme Court of the United States

OCTOBER TERM, 1985

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

AMERICAN HOSPITAL ASSOCIATION, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

JOINT APPENDIX

BENJAMIN W. HEINEMAN, JR.
CARTER G. PHILLIPS
VINCENT F. PRADA
SIDLEY & AUSTIN
1722 Eye Street, N.W.
Washington, D.C. 20006
(202) 429-4000
Counsel for American Medical Association, et al.

STUART M. GERSON
EPSTEIN, BECKER, BORSODY & GREEN
1140 19th Street, N.W.
Washington, D.C. 20036
(202) 861-0900
Counsel for American Hospital Association, et al.

CHARLES FRIED
Acting Solicitor General
Department of Justice
Washington, D.C. 20530
(202) 633-2217
Counsel for Petitioner

PETITION FOR A WRIT OF CERTIORARI FILED MARCH 27, 1985
CERTIORARI GRANTED JUNE 17, 1985

BEST AVAILABLE COPY

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TABLE OF CONTENTS*

	Page
1. District Court docket entries in *American Hospital Association, et al.* v. *Heckler, No. 83 Civ. 2638*	1
2. District Court docket entries in *American Medical Association* v. *Heckler*, No. 84 Civ. 1724	5
3. Court of Appeals docket entries in Nos. 84-6211, 84-6213 (consolidated cases)	8
4. Department of Health and Human Services, "Nondiscrimination on the Basis of Handicap; Procedures and Guidelines Relating to Health Care for Handicapped Infants; Final Rule," 49 Fed. Reg. 162 (January 12, 1984)	11

*The opinions of the district court and the court of appeals are printed in the appendix to the petition for writ of certiorari and have not been reproduced.

Contents—Continued: Page

5. Department of Health and Human Services, "Discriminating Against the Handicapped By Withholding Treatment or Nourishment; Notice of Health Care Providers," 47 Fed. Reg. 26027 (June 16, 1982) 127

6. Complaint in *American Medical Association* v. *Heckler*, filed March 12, 1984 129

7. Amended Complaint in *American Hospital Association, et al.* v. *Heckler*, filed March 12, 1984 151

8. Plaintiffs' Motion for Preliminary Injunction filed in *American Hospital Association, et al.* v. *Heckler*, filed March 12, 1984 160

9. Affidavit of Richard L. Epstein 162

10. Affidavit of Peter A. M. Auld, M.D. 166

11. Affidavit of Rita Gilman Harper, M.D. 172

12. Affidavit of Paul M. Rosenberg 178

13. Affidavit of Norman B. Urmy 183

14. Excerpt from President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, "Deciding to Forego Life-Sustaining Treatment," pp. 223-229 187

15. Order Granting Petition for Certiorari 195

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

Civil Action No. 83 Civ. 2638 (CLB)
AMERICAN HOSPITAL ASSOCIATION,
ON BEHALF OF ITS MEMBER HOSPITALS,
HOSPITAL ASSOCIATION OF NEW YORK STATE,
ON BEHALF OF ITS MEMBER HOSPITALS,
STRONG MEMORIAL HOSPITAL OF THE
UNIVERSITY OF ROCHESTER, PLAINTIFFS

v.

MARGARET M. HECKLER, SECRETARY, UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

RELEVANT DOCKET ENTRIES

DATE	NR.	PROCEEDINGS
04-06-83	1	Fld complaint & issued summons & notice purs to 28:636(c)
4-6-83	2	Fld. ORDER TO SHOW CAUSE FOR P.I. AND TRO ... ordered that pending the hearing of pl: application to a P.I. the defts. are temporarily restrained and enjoined from enfor. 45 CFR 84.61(a)(b) solely to the extent it purports to require the posting of notice upon the premises of voluntary or municipal hospitals within N.Y.S. etc. further that security to be posted by the pltffs is not necessary ... BRIEANT, J. Issued 4-6-83 Ret. 4-18-83.
4-15-83	4	Fld. pltffs. memo in support of motion for P.I. and TRO.
4-15-83	—	Fld. Memo-Endorsed on doc. #2 ... motion granted. Settle a proposed injunction order on 3 days notice. See Transcript of hearings this date and previously. BRIEANT, J.

4-28-83	5	Fld. ORDER that this action is transferred to the Suspense Docket of this Court, pending resolution of litigation presently pending in the Court of Appeals for the District of Columbia or pending further order of this Court. BRIEANT, J. mn
5-4-83	6	Fld. PRELIMINARY INJUNCTION ... Ordered that sufficient reason having been shown there for the defts are enjoined and restrained from enforcing 45 CFR 84.61 within N.Y.S. during the pendency of this action or until further order of this Court. Bond is unnecessary. BRIEANT, J. mn
3-12-84	10	FLd. pltffs. notice of motion & affdvt for an order of preliminary injunction. Ret. 3-23-84
3-12-84	11	Fld. pltffs. memo of points and authorities in support of motion.
3-12-84	12	Fld. AMENDED COMPLT.
3-22-84	13	Fld. defts opposition to pltffs motion for preliminary injunction.
3-23-84	14	Fld. pltffs reply to defts opposition to motion for preliminary injunction.
3-23-84	15	Fld. ORDER that the action is transferred from the Suspense Docket to active docket and this action and 84 civ 1724 CLB are consolidated for purposes. All papers hereafter filed shall be docketed under 83 civ BRIEANT, J. mn
5-18-84	18	Fld. pltffs supplemental memo on effect of Grove City College V. Bell.
5-18-84	19	Fld. pltffs supplemental memorandum.
5-23-84	20	Fld. MEMO & ORDER...Settle final declaratory judgment on 5 days notice. BRIEANT, J. mn
6-11-84	23	Fld. FINAL JUDGMENT...Ordered that the Final regulation and all actions implement it are declared invalid and unlawful as exceeding the scope of defts authority under section 504 of the Rehabilitation Act

		of 1973, 29 USC 794, etc. Defts are permanently enjoined from any further implementation of the Final Regulation with respect to any program or activity receiving Federal financial assistance...etc. BRIEANT, J, JUDGMENT ENTERED 6-11-84...CLERK (EOD on 6-12-84.)
6-11-84	24	Fld. defts Ex parte motion for order extending the time to submit counterproposed judgment.
6-11-84	—	Fld. Memo-Endorsed on doc. #24...This is a totally useless motion which should be and is denied, etc. BRIEANT, J.
7-9-84	28	Fld. defts NOTICE OF APPEAL to the USCA-Second Circuit from the judgment entered on 6-11-84. Mailed notice to Benjamin W. Heineman, Jr at 1722 Eye St. N.W. Washington D.C. 20006, Newton N. Minow at One First National Plaza, Chicago, Illinois 60603, Steven M. Bierman at 520 Madison Avenue, NYC 10022, Stuart M. Gerson at 1140 19th Street N.W. Suite 9000, Washington D.C. 20036 and Lawrence Washburn, Jr at 521 5th Ave. NYC 10175 on 7-11-84.
7-11-84	—	COPY OF NOTICE OF APPEAL FORWARDED TO DISTRICT JUDGE AND COPY OF NOTICE OF APPEAL AND DOCKET ENTRIES TO C.A.
7-11-84	29	Fld. pltffs notice of motion for an order staying until no later than 30 days after appellate disposition of this case the submission by AHA of documentary material in support of its application for an award of attys fees, etc. Ret. 7-23-84
7-11-84	30	Fld. pltffs memo in support of motion for an order staying submission, etc.
7-11-84	31	Fld. pltffs application for award of attys fees and costs.

7-17-84	35	Filed Order...Ordered that the submission by AHA of documentary or other material in support of its application for an award of attys' fees is stayed until no later than 30 days after final appellate disposition of this case...BRIEANT.

IN THE UNITED STATES DISTRICT COURT FOR
THE SOUTHERN DISTRICT OF NEW YORK

Civil Action No. 84 Civ. 1724 (CLB)

AMERICAN MEDICAL ASSOCIATION,
AMERICAN HOSPITAL ASSOCIATION,
HOSPITAL ASSOCIATION OF NEW YORK STATE,
AMERICAN COLLEGE OF OBSTETRICIANS
AND GYNECOLOGISTS,
ASSOCIATION OF AMERICAN MEDICAL COLLEGES,
AMERICAN ACADEMY OF FAMILY PHYSICIANS,
HUBERT A. RITTER, M.D.,
PETER A.M. AULD, M.D.,
RITA GILMAN HARPER, M.D.,
ROY HOWARD PETRIE, M.D.,
PLAINTIFFS

v.

MARGARET M. HECKLER, SECRETARY, DEPARTMENT
OF HEALTH AND HUMAN SERVICES

RELEVANT DOCKET ENTRIES

DATE	NR.	PROCEEDINGS
3-12-84	1	Filed Complaint-Issued Summons & Notice purs. to 28 USC 636(c).
3-12-84	3	Filed Pltffs' Notice of Motion for an Order granting preliminary injunction. Motion returnable on 03-23-84.
3-12-84	4	Filed Memorandum of Points & Authorities in Support of Pltffs' Motion for Preliminary Injunction.
3-12-84	4	Filed Appendices in Support of Pltffs' Motion for Preliminary Injunction.
3-12-84	6	Filed Pltffs' Notice of Motion Consolidating the instant case with American Hospital Association vs Heckler. Motion returnable on 03-23-84.

3-12-84	7	Filed Memorandum of Points & Authorities in Support of Pltffs' Motion for Consolidation.
3-14-84	8	FLD. NOTICE OF ASSIGNMENT TO JUDGE BRIEANT. Mn.
3-15-84	9	Fld. pltffs. SDNY General Rules Rule 9 Certification.
3-22-84	11	Fld. defts memo of points and authorities in opposition to motion for preliminary injunction.
3-23-84	12	Fld. pltffs reply memo of points and authorities in support of motion for a preliminary injunction.
3-23-84	—	Fld. ORDER that this action is consolidated with 83 civ 2638 CLB for all purposes and all papers shall be filed and docketed under 83 civ BRIEANT, J. mn
6-11-84	13	Fld. FINAL JUDGMENT...Ordered that defts are permanently enjoined from any further implementation of the Final Regulation with respect to any program or activity receiving Federal financial assistance. See 29 USC 794 and 29 USC 706(14), etc. BRIEANT, J. JUDGMENT ENTERED 6-11-84. CLERK. (EOD on 6-12-84)
7-9-84	15	Fld. defts NOTICE OF APPEAL to the USCA-Second Circuit from the judgment entered on 6-11-84. Mailed notice to Benjamin W. Heineman, Jr at 1722 Eye ST. NW. Washington D.C. 20006, Newton N. Minow at 1 First National Plaza, Chicago, Illinois 60603, Steven M. Bierman at 520 Madison Avenue, NYC 10022, Stuart M. Gerson at 1140 19th St. NW Washington DC 20036 and Lawrence Washburn, Jr at 521 Fifth Ave. NYC 10175 on 7-11-84
7-11-84	—	COPY OF NOTICE OF APPEAL FORWARDED TO DISTRICT JUDGE AND

		COPY OF NOTICE OF APPEAL AND DOCKET ENTRIES TO C.A.
7-11-84	16	Fld. pltffs notice of motion for an order of attys fees, etc. Ret. 7-23-84
7-11-84	17	Fld. pltffs memo of points and authorities in support of motion.
12-11-84	18	Fld. pltffs application for award of attys fees and costs.

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

Docket No. 84-6211

AMERICAN HOSPITAL ASSOCIATION,
ON BEHALF OF ITS MEMBER HOSPITALS,
HOSPITAL ASSOCIATION OF NEW YORK STATE,
ON BEHALF OF ITS MEMBER HOSPITALS,
STRONG MEMORIAL HOSPITAL OF
THE UNIVERSITY OF ROCHESTER,
PLAINTIFFS-APPELLEES

v.

MARGARET M. HECKLER, SECRETARY, UNITED STATES
DEPARTMENT OF HEALTH & HUMAN SERVICES

Docket No. 84-6213

AMERICAN MEDICAL ASSOCIATION,
AMERICAN HOSPITAL ASSOCIATION,
HOSPITAL ASSOCIATION OF NEW YORK STATE,
AMERICAN COLLEGE OF OBSTETRICIANS
AND GYNECOLOGISTS,
ASSOCIATION OF AMERICAN MEDICAL COLLEGES,
AMERICAN ACADEMY OF FAMILY PHYSICIANS,
HUBERT A. RITTER, M.D.
PETER A.M. AULD, M.D.
RITA GILMAN HARPER, M.D.
ROY HOWARD PETRIE, M.D.,
PLAINTIFFS-APPELLEES

v.

MARGARET M. HECKLER, SECRETARY, DEPARTMENT OF
HEALTH AND HUMAN SERVICES

RELEVANT DOCKET ENTRIES

DATE	FILINGS—PROCEEDINGS
7-12-84	Copy of district court docket entries and notice of appeal on behalf of appellant Heckler filed (& in 84-6213)

8-3-84	Appellant motion for an original hearing in banc filed. (w/pfs)
8-10-84	Appellees affidavit in opposition to appellant motion for an original hearing in banc filed. (w/pfs)
8-10-84	Appellees AMA response in opposition to appellants' motion for an original hearing in banc filed. (w/pfs)
8-22-84	Order denied appellant motion for an original hearing in banc filed.
9-20-84	Record on appeal filed. (original papers of the district court proceedings)
9-26-84	Appellant motion for summary disposition without briefing or oral argument filed. (w/pfs)
10-2-84	Appellant brief filed w/ps (by mail)
10-9-84	Appellees AMA opposition to defendant appellants motion for summary disposition without briefing or oral argument w/pfs filed.
10-09-84	Appellees AHA response to defendant appellants motion for summary disposition without briefing or oral argument w/pfs filed.
10-25-84	Appellee AHA briefs filed (w/pfs) (page proofs)
10-25-84	Appellee AMA briefs filed (w/pfs) (page proofs)
11-2-84	Appellant HECKLER motion for extension of time for filing reply brief filed pfs.
11-7-84	Order granted appellant motion to extend time to file reply brief filed (Endorsed on motion filed 11-2-84)
11-7-84	Appellees American Medical Assoc. et al. brief filed w/ps (& in 84-6213)
11-8-84	Appellees American Hospital Assoc. et al. brief filed w/ps (& in 84-6213)
11-8-84	Deferred Joint-appendix filed w/ps (& in 84-6213)
11-16-84	Appellant Margaret Heckler reply brief filed (w/pfs)
12-27-84	Judgment Affirmed, detailed court order without opinion filed (& in 84-6213) (JON, GCP, JWP)
1-18-85	Mandate Issued (judgment)
4-8-85	Notice of filing of petition for writ of certiorari filed on behalf of M. Heckler (S.C. #84-1529)

6-19-85	Certified copy of order by Supreme Court granting petition for writ of certiorari filed

[49 Fed. Reg. 1622 (Jan. 12, 1984)]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 84

Nondiscrimination on the Basis of Handicap; Procedures and Guidelines Relating to Health Care for Handicapped Infants

AGENCY: Office of the Secretary, HHS.

ACTION: Final rules.

SUMMARY: These are final rules on procedures and guidelines relating to nondiscrimination on the basis of handicap in connection with health care for handicapped infants. These rules are issued under the authority of section 504 of the Rehabilitation Act of 1973, which prohibits discrimination on the basis of handicap in programs and activities receiving Federal financial assistance.

EFFECTIVE DATE: February 13, 1984.

FOR FURTHER INFORMATION CONTACT: Susan Shaloub, Office for Civil Rights, Department of Health and Human Services, 330 Independence Avenue, SW., Room 5514, Washington, D.C. 20201; telephone (202) 245-6585. TDD No. (202) 472-2916.

SUPPLEMENTARY INFORMATION:

I. Synopsis

These rules are the product of a careful analysis of nearly 17,000 comments submitted to the Department during the comment period provided by the proposed rules of July 5, 1983. On the basis of this analysis, the Department has made significant modifications to the proposed rules. These modifications are designed to establish a framework under which the substantial controversy that has attended the Department's efforts to strengthen enforcement of section 504 in this area can be replaced by a more cooperative effort involving the Federal Government, the medical community, private advocacy groups and state governments.

These final rules continue the Department's efforts to put in place an effective mechanism for enforcing section 504 in connection with health care for handicapped infants.

But they also initiate new efforts to make unnecessary the use of those Federal enforcement mechanisms by encouraging hospitals to establish policies and procedures to implement the principle that treatment decisions for handicapped infants be based on reasonable medical judgments, and medically beneficial treatment not be withheld solely on the basis of an infant's present or anticipated mental or physical impairments.

In seeking to forge a cooperative approach, the Department is encouraged by the recent development of "Principles of Treatment of Disabled Infants" by the following major medical and disability organizations: American Academy of Pediatrics, National Association of Children's Hospitals and Related Institutions, Association for Retarded Citizens, Down's Syndrome Congress, Spina Bifida Association of America, American Coalition of Citizens with Disabilities, the Association for the Severely Handicapped, American Association on Mental Deficiency, and American Association of University Affiliated Programs for the Developmentally Disabled. Announced November 29, 1983, in Washington, D.C., these principles state:

> When medical care is clearly beneficial, it should always be provided.* * * Considerations such as anticipated or actual limited potential of an individual and present or future lack of available community resources are irrelevant and must not determine the decisions concerning medical care. The individual's medical condition should be the sole focus of the decision. These are very strict standards.
>
> It is ethically and legally justified to withhold medical or surgical procedures which are clearly futile and will only prolong the act of dying. However, supportive care should be provided, including sustenance as medically indicated and relief of pain and suffering. The needs of the dying person should be respected. The family also should be supported in its grieving.
>
> In cases where it is uncertain whether medical treatment will be beneficial, a person's disability must not be

> the basis for a decision to withhold treatment. * * * When doubt exists at any time about whether to treat, a presumption always should be in favor of treatment.

In the issuance of these final rules, the Department seeks to build upon the spirit of cooperation underlying this landmark statement of principles. The major elements of the final rules are as follows:

First, the Department adopts the recommendation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research that the Federal government encourage hospitals to establish review procedures concerning life and death decisions affecting seriously ill newborns. The rules include a model Infant Care Review Committee to assist hospitals in this effort.

Second, the rules require the posting in hospitals of an informational notice regarding the legal rights of handicapped infants. The notice requirements have been revised to permit hospitals to highlight their own policies and internal review procedures, in addition to the federal law and government contact points.

Third, the rules require that state child protective services agencies have established procedures for applying their own state laws protecting children from medical neglect.

Fourth, the appendix to the rules sets forth interpretative guidelines for applying the law in these cases. These guidelines restate the Department's interpretation that section 504 requires that health care providers not withhold nourishment or medically beneficial treatment from a handicapped infant solely on the basis of present or anticipated physical or mental impairments, but it does not interfere with reasonable medical judgments, nor require the provision of futile treatments.

Fifth, the appendix to the rules sets forth guidelines for HHS investigations of alleged civil rights violations relating to health care for handicapped infants. These guidelines provide for the participation of hospital Infant Care Review Committees, the avoidance of unnecessary investigations, the involvement of qualified medical consultants, and the protection of confidential information.

The Department hopes the issuance of these rules, which become effective in 30 days, will end the controversy that has surrounded their development. But more importantly, it is hoped the rules will foster a new process of cooperative efforts and sensible approaches to advance the principle that life and death medical treatment decisions be based on informed judgments of medical benefits and risks, and not on stereotypes and prejudices against handicapped persons.

II. Background

On April 30, 1982, President Reagan instructed the Secretary of Health and Human Services:

> to notify health care providers of the applicability of section 504 of the Rehabilitation Act of 1973 to the treatment of handicapped patients. That law forbids recipients of federal funds from withholding from handicapped citizens, simply because they are handicapped, any benefit or service that would ordinarily be provided to persons without handicaps. Regulations under this law specifically prohibit hospitals and other providers of health services receiving federal assistance from discriminating against the handicapped.
>
> * * * * *
>
> Our nation's commitment to equal protection of the law will have little meaning if we deny such protection to those who have not been blessed with the same physical or mental gifts we too often take for granted. I support federal laws prohibiting discrimination against the handicapped, and remain determined that such laws will be vigorously enforced.

The President's instructions followed reports of the death, in Bloomington, Indiana, of an infant with Down's syndrome, from whom available surgical treatment to repair a detached esophagus was withheld.

On May 18, 1982, HHS issued to approximately 7,000 hospitals a notice stating:

> Under section 504 it is unlawful for a recipient of federal financial assistance to withhold from a handicapped infant nutritional sustenance or medical or surgical treatment required to correct a life-threatening condition if: (1) the withholding is based on the fact that the infant is handicapped; (2) the handicap does not render

the treatment or nutritional sustenance medically contraindicated.

Soon after this notice, the HHS Office for Civil Rights (OCR) established expedited investigative procedures to deal with any case of a suspected discriminatory withholding of lifesustaining nourishment or medical treatment from a handicapped inf[illegible].

On March 7, 1983, HHS issued, with a scheduled effective date of March 22, 1983, an interim final rule requiring recipient hospitals to post "in a conspicuous place" in pertinent wards a notice advising of the applicability of section 504 and the availability of a telephone "hotline" to report suspected violations of the law.

On April 14, 1983, the Honorable Gerhard Gesell, United States District Judge for the District of Columbia, declared the interim final rule invalid on the grounds that it was "arbitrary and capricious" and that there was inadequate justification for waiving a public comment period prior to issuance of the regulation. *American Academy of Pediatrics* v. *Heckler*, 561 F. Supp. 395 (D.D.C. 1983). Judge Gesell declined to order the Department to discontinue use of the hotline.

On July 5, 1983, HHS issued a proposed rule in which the notice requirement was revised; provisions were added concerning state child protective service agencies; an appendix of standards and examples was added; and a 60-day comment period was provided. 48 FR 30846.

The Department received 16,739 comments, of which 16,331 (97.5%) supported the proposed rule, and 408 (2.5%) opposed it. Other aggregate descriptions are:

—Of 322 nurses, 314 (97.5%) supported, and 8 (2.5%) opposed it.

—Of 141 pediatricians or newborn care specialists, 39 (27.7%) favored, and 102 (72.3%) opposed it.

—Of 253 physicians, not including pediatricians or newborn care specialists, 140 (55.3%) favored, and 113 (44.7%) opposed it.

—Of 137 comments from hospital officials and medical, hospital, nursing and other health related association, 31 (22.6%) supported and 106 (77.4%) opposed it.

—Of 77 comments from associations representing the handicapped, all supported the proposed rule.

—Of 100 parents of handicapped persons, 95 (95%) supported and 5(5%) opposed it.

In addition to the written comments received, a number of meetings were held after issuance of the proposed rule with representatives of interested groups. The principal HHS officials involved in these meetings were the Under Secretary and the Surgeon General. Minutes of these meetings were kept and have been included in the public comment file.

Every comment was read and analyzed. Readers determined whether the commenter was in favor of, or opposed to, the proposed rule and identified particular points made by the commenter. The decisions made by the Department in connection with the rule are based not on the volume of comments advancing any point, but on thorough consideration of the merits of the comments submitted.

III. Provisions of the Final Rules

A. INFANT CARE REVIEW COMMITTEES

The March 1983 report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research included the following recommendation:

> The Commission concludes that hospitals that care for seriously ill newborns should have explicit policies on decisionmaking procedures in cases involving life-sustaining treatment for these infants.... Such policies should provide for internal review whenever parents and the attending physician decide that life-sustaining therapy should be foregone....
>
> Such a review could serve several functions and the review mechanism may vary accordingly. First, it can verify that the best information available is being used. Second, it can confirm the propriety of a decision that providers and parents have reached or confirm that the range of discretion accorded to the parents is appropriate. Third, it can resolve disputes among those involved in a decision, if necessary, by siding with one party or another in a dispute. Finally, it can refer cases to public agencies (child protection services, probate courts, or prosecuting attorneys) when appropriate.

In response to a question included in the preamble, the Department received many comments regading hospital review boards. Many commenters who expressed opposition to the rule, particularly health care providers, expressed a strong preference for the hospital review board approach over the proposed rule or any implementation or enforcement of section 504. Others opposed hospital review boards, particularly as an alternative to the proposed rule and existing HHS procedures.

The American Academy of Pediatrics, which submitted the most detailed proposal, suggested, as an alternative to the proposed rule, that all hospitals, as a condition of participation in the Medicare program (not as a requirement of section 504), establish a review committee. Under this proposal (also endorsed by the National Association of Children's Hospitals and Related Institutions, and in concept, the American Hospital Association) the committee would have three functions: (1) To develop hospital policies and guidelines for management of specific types of diagnoses; (2) to monitor adherence through retrospective record review; and (3) to review, on an emergency basis, specific cases when the withholding of life-sustaining treatment is being considered. When the committee disagreed with a parental or physician decision to withhold treatment, the case would be referred to the appropriate court or child protective agency, and treatment would be continued pending a decision. Committee membership would include a hospital administrator, a representative of a disability group, a lay community member, a member of the hospital's medical staff, and a practicing nurse.

Among the arguments advanced in favor of the creation of hospital review boards, as a substitute for the approach set forth in the proposed rule, were:

(a) They would represent a cooperative approach between the government and the health care community, rather than a confrontational approach.

(b) They would provide a vehicle by which facility "self-evaluations" can be conducted.

(c) They would assure an indepth review by persons of varied perspectives of individual, complex cases involving critically ill infants.

(d) They would provide a mechanism for ensuring that hospitals, physicans and parents are informed of the most recent medical information concerning treatment of handicapped infants and of community services, counselling, parent support groups, and such alternative care options as adoption, foster care, and other out-of-home placements.

(e) They would lead to the involvement of child protective agencies and of the courts where it is indicated that the interests of the child are not being served.

Many commenters who expressed support for the proposed rule also expressed strong opposition to the alternative approach of hospital review boards because:

(a) Such boards cannot replace State and federal government responsibilities to protect the rights of citizens. The use of review boards would not assure that all individuals with disabilities would receive nondiscriminatory treatment as guaranteed by section 504.

(b) Such boards are virtually untested as a viable mechanism to protect handicapped infants from discriminatory practices.

A number of commenters, including the American Medical Association, the Catholic Health Association, the Federation of American Hospitals, the American College of Hospital Administrators, the American College of Physicians, the American Nurses Association, and other medical groups, expressed support for the concept of review boards, but opposed any mandate that review boards be established. The AMA added:

> While we do not support federal intervention in treatment decisions concerning seriously ill newborns, the attention brought about by the government's action should provide a continued stimulus to develop mechanisms to deal with these sensitive matters without the intrusion of the federal government into an area where it does not belong.

Response

The Department believes there is much merit in many of the comments submitted both in favor of, and in opposition to, utilization of hospital review boards to assist in the devel-

opment of standard policies and protocols and to review individual cases. The Department's conclusions are as follows.

First, the Department believes review committees cannot be given an exclusive role in reviewing medical decisions concerning the withholding or withdrawal of medical or surgical treatments from handicapped infants, and thus, cannot accept the proposal of hospital review boards as a *substitute* for mechanisms to enforce section 504.

The Department does not seek to take over medical decisionmaking regarding health care for handicapped infants. HHS agrees that the best decisionmakers are generally the parents and the physicians directly involved. However, there is, and must be, a framework within which the decisionmakers, the parents and physicians, operate.

That framework is established by laws. With respect to health care professionals providing services under programs or activities receiving federal financial assistance, the framework includes section 504, which prohibits discrimination on the basis of handicap in programs or activities receiving Federal financial assistance. With respect to parents, the laws are state laws establishing limitations on parental authority. With respect to both the federal law and the respective state laws, each specifically provides implementation mechanisms involving government agencies.

The fundamental issue involved in deciding whether review boards should be a substitute for enforcement of section 504 is whether the legal framework within which the decisionmaking parents and physicians are supposed to function (and generally do function) will be utilized.

Under the proposal that review boards act in lieu of government, whether physicians or hospital review boards adhere to the principles of section 504 would be determined by those physicians and boards alone. Whether parents, physicians, or review boards adhere to state laws on the limitations of parental authority would be decided by the same physicians and boards. Whether they ever utilize the implementation schemes established by law to ensure that those principles are adhered to would also be decided by those parents, physicians, and review boards.

The Department concludes that the essential element of this alternative proposal—that it separates the process from the established legal framework governing decisionmaking by parents and physicians, with no meaningful provision to ensure that they function in accord with this framework—makes the proposal unacceptable as a substitute for the proposed rule. This alternative proposal simply does not provide sufficient safeguards that the requirements of section 504 will be met. Because section 504 is applicable to the provision of health care services to handicapped infants in programs and activities receiving Federal financial assistance, the Department believes it would not be justifiable for the Department to refrain from exercising a regulatory role to enforce the statute.

Second, the Department concludes that, although unacceptable as a substitute, review boards can be very valuable. The Department agrees with the rationale of the President's Commission and many commenters that input from a committee that includes individuals with medical expertise and people with non-medical perspectives and that is guided by proper standards and protocols can be very helpful in bringing about informed, enlightened and fair decisionmaking regarding these difficult issues. The Department, therefore, adopts the recommendation of the President's Commission that the government encourage establishment of hospital review boards.

Third, the Department concludes that the creation of hospital review boards should not be mandated by the Federal government. The Department agrees with the President's Commission that because review boards are "largely untried", they are not so demonstrably effective as to justify making them mandatory for nearly 7,000 hospitals nationwide. Also, there would be very substantial practical problems in seeking to enforce such a mandate with respect to so many hospitals. To make such a mandate viable, it would have to be accompanied by detailed standards on how to organize and operate the committee. The Department agrees with the President's Commission that flexibility is needed for each hospital to consider the best approach for itself. For example, the review board procedures may be

unnecessary for small or rural hospitals that rarely encounter cases involving severely impaired newborns and that handle such cases by immediately transferring the infant to the appropriate specialty hospital.

In addition, in view of the strong opposition by major medical organizations to mandatory committees, there would likely be protracted legal proceedings challenging the regulation, whether adopted pursuant to section 504 or pursuant to authority under the Social Security Act to establish conditions of participation and standards for the Medicare and Medicaid programs.

For these reasons, the Department has concluded that Infant Care Review Committees should be encouraged, but not mandated by the federal government.

Fourth, the Department concludes that the establishment of review boards will be facilitated by the development of a model committee. Therefore, § 84.55(f) of the rules sets forth a model Infant Care Review Committee (ICRC). This model calls for broad representation and significant involvement of the ICRC in developing standard policies and protocols for the hospital and in promptly reviewing specific cases. The model is based substantially on comments submitted by the American Academy of Pediatrics.

The Department has revised the Academy's model somewhat to underscore that the purpose of the ICRC is to advance the basic principles embodied in section 504, the recommendations of the President's Commission and the landmark "Principles of Treatment of Disabled Infants." The Department has also revised the Academy's model to provide, in connection with review of specific cases, for the designation of one member of the ICRC as "special advocate" for the infant. While recognizing that all members of the ICRC should be advocates for the best interests of the infant, the role of the special advocate will be to ensure that all considerations in favor of the provisions of life-sustaining treatment are fully evaluated and considered. As the President's Commission stated, "it is all too easy to undervalue the lives of handicapped infants." The special advocate feature of the model ICRC provides a mechanism to counteract this tendency.

This model is also consistent with the recommendations of the President's Commission and the comments of the American Hospital Association and other medical organizations. The Department also acknowledges the comment of the American Medical Association that the government's actions provide "a continued stimulus" for the medical community "to develop mechanisms to deal with these sensitive matters." HHS strongly encourages medical organizations to follow through on their suggestions and provide all possible assistance to their member institutions and medical professionals in establishing and operating these ICRC's.

B. INFORMATIONAL NOTICE

The proposed rules required that recipient hospitals post "in a conspicuous place in each nurse's station" of appropriate wards a notice stating:

> DISCRIMINATORY FAILURE TO FEED AND CARE FOR HANDICAPPED INFANTS IN THIS FACILITY IS PROHIBITED BY FEDERAL LAW
>
> * * * * *
>
> Any person having knowledge that a handicapped infant is being discriminatory denied food or customary medical care should immediately contact:
> Handicapped Infant Hotline
>
> * * * * *
>
> Failure to feed and care for infants may also violate the criminal and civil laws of your state.

A number of commenters expressed a concern that the posting of the required notice would itself have a disruptive effect on the provision of health care to newborn infants by creating the impression to an infant's parents, already in a very stressful situation, that the physician, nursing staff, and hospital should not be trusted to provide proper care to their child. In connection with this point, the Catholic Health Association suggested that hospitals be permitted to use an alternative notice allowing the hospital to state its agreement with the policy of nondiscrimination and indicate the appropriate hospital contact person. Another comment suggested alternatives to posting, such as placing the notice

on the admitting document or on consent forms used by the hospital.

Some commenters considered the wording of the notice very ambiguous in its references to "discriminatory failure" and "customary medical care" and in its failure to make reference to futile treatments, deference to legitimate medical judgments, the nonapplicability of section 504 to parental decisions, and many distinctions and nuances relating to the applicability of section 504 in this context.

Other criticisms were that the words "should immediately contact" improperly implied a legal obligation to report; the reference to "this facility" implied prior misconduct by that facility; and the reference to violations of "the criminal and civil laws of your state" is inappropriate because it does not relate to the purpose of the notice to inform people about civil rights protections.

A number of commenters suggested additions to the notice, including: a reference to the sanctions for noncompliance; express inclusion of handicapped infants born alive after abortions; reference to physical, mental, or emotional abuse or injury or withholding of fluids, oxygen, medications, warmth, and routine nursing care; and a statement that callers are not required to identify themselves.

Other commenters urged that hospitals be required to notify HHS that the notice has been posted.

Response

In an effort to accommodate many of these concerns, the Department has made a number of changes regarding the wording of the informational notice and the locations where it is to be posted. However, the Department remains convinced of the need for a notice to advise individuals in a position to know about potentially discriminatory conduct of the requirements of the law and of the mechanisms available to report suspected violations expenditiously so that, should a violation be occurring, corrective action can be taken in time to save the infant's life.

In many other contexts of civil rights enforcement and enforcement of scores of other statutes, speed is not essential because the victim of discrimination can be essentially "made

whole" through reinstatement in a job, admission to a school or hospital, retroactive benefit payments, or the like. However, in the context of life and death medical decisons, the matter must be handled with the utmost urgency. For this reason, the Department continues to believe that it is essential to meaningful implementation of the requirements of section 504 to have a mechanism for immediate reports of suspected violations.

However, the Department has concluded that it can, without detracting from this overriding objective, eliminate the unintended adverse effects of the notice many commenters perceived. Therefore, the informational notice requirements set forth in § 84.55(b) reflect significant modifications from those set forth in the proposed rules.

First, the Department has adopted the suggestion of the Catholic Health Association that hospitals be permitted to post a notice reflecting that the hospital's policy is consistent with the nondiscrimination requirements of section 504 and that the hospital also has a mechanism to review suspected noncompliance with this policy. This change eliminates any perception that the notice implies improper conduct by the hospital.

The only requirement contained in the rule for the use of this notice (identified in the regulation as "Notice A") is that the content of the notice be truthful as it relates to that hospital. To be truthful, the hospital must have a policy that nourishment and medically benefical treatment, as determined with respect for reasonable medical judgments, should not be withheld from handicapped infants solely on the basis of their present or anticipated mental or physical impairments. Furthermore, the hospital must have a procedure for review of treatment deliberations and decisions concerning health care for handicapped infants. Also, so that potential callers will be assured that the hospital's procedures will be implemented in good faith, the hospital's policies must provide for the confidentiality of the identity of, and prohibitions of retaliation against, potential callers who, in good faith and nonmaliciously, provide information about possible noncompliance. A hospital need not, in order to post Notice A, have an Infant Care Review Committee in con-

formance with the model ICRC, nor forego management prerogatives with respect to anyone who might abuse the hospital's procedures by, for example, willfully making false or malicious calls. Hospitals for which the content of "Notice A" is not truthful must post the notice identified as "Notice B."

Second, the requirement regarding the location where copies of the notice must be posted has been changed. Consistent with the Department's intent to target the notice to nurses and other health care professionals, the proposed rule required that the notice be posted at the nurses' stations of appropriate wards, rather than more generally in the wards as had been stated in the March interim final rule. In view of the concern expressed by a number of commenters that posting in the nurses' stations would continue to make the notice conspicuous to distressed parents, the final rules do not require that copies of the notice be posted at nurses' stations. Rather, the notice is to be posted at any location(s) where nurses and other medical professionals who are engaged in providing health care related services to infants will be aware of the content of the notice. Locations such as locker rooms and lounge areas will suffice as long as placement in these locations ensures that the appropriate personnel will see the notice. Under these circumstances the notice would not have to be posted at nurse's stations or any other location where posting would have adverse effects on parents. The number of copies which must be posted in the hospital is similarly determined on the basis of ensuring that the appropriate personnel will see it.

Third, in view of this more specific targeting, the size of the notice has been reduced from the 8½ × 11 inches requirement in the proposed rule (and the 17 × 14 inch notices distributed in connection with the March rule) to 5 × 7 inches.

Fourth, the wording of the informational notice has been revised in connection with the language which attempts to convey in simple terms the basic protection of the law. The new language reflects the law's deference to reasonable medical judgments, refers to "medically beneficial treatment" and clarifies that the concept of handicapped discrimination

relates to decisions made solely on the basis of present or anticipated mental or physical impairments. The reference in the text of the notice and elsewhere in the rules to "present or anticipated mental or physical impairments" is based on the definition of "handicapped person" in existing regulations, 45 CFR 84.3(j). The Department believes this phrase conveys a better understanding than use of the word "handicap."

The Department has also changed the heading of the notice to eliminate what many perceived to be a negative statement. The revised notice adopts the same heading. "Principles of Treatment of Disabled Infants", adopted by the coalition of leading disability and medical organizations in their landmark statement of principles.

In seeking to compose the wording of the notice, the Department has sought to set forth a simple, understandable, and accurate description of the requirement of the law. To a significant degree, the application of section 504 in this context defies a simple and precise restatement. The wording of the notice, however, does not establish a legally mandated rule of conduct; it merely conveys information. In recognition of the impossibility of setting forth a statement that covers all possible dimensions and nuances of the statute, the notice advises that callers may obtain further information by calling the designated contact points.

The Department believes this statement resolves many of the concerns regarding ambiguity of the prior version of the notice without becoming so cumbersome and complicated that it confuses more than it informs.

Concerning other comments, the Department is not adopting the suggestion that hospitals be required to notify HHS that the notice has been posted. There are insufficient benefits accruing from establishing a mechanism for checking off approximately 7,000 unverified notifications of posting to justify the administrative burden on the Department and recipients.

In addition, consistent with the objective of targeting the notice to nurses and other medical professionals, and in view of concerns about frightening parents, the Department is not adopting the suggestion that the nondiscrimination notice be

required on hospital admission or consent forms. However, the Department encourages hospitals and Infant Care Review Committees to consider seriously developing some written information for parents with respect to hospital policies and procedures in connection with this issue. Such information could include an explanation of rights and responsibilities of parents, infants, and hospitals, the operation of the ICRC, available social services, and other pertinent information.

The Department is also not adopting numerous suggestions for additions to the notice because they are unnecessary and would make the notice cumbersome and possibly confusing. Statements concerning the existence of sanctions for noncompliance, the applicability of section 504 to infants born alive after abortions, the lawfulness of withholding futile treatments, and the applicability of section 504 to a wide range of aspects of medical care are all quite correct, but their inclusion in the notice is unnecessary.

The Department is not adopting the suggestion that the notice state that callers are not required to identify themselves. Although the Department will take appropriate follow-up action on anonymous calls that convey credible and specific information, the Department does not wish to encourage callers to remain anonymous because there is great value in having the ability to recontact the complainant as the inquiry or investigation progresses. The Department believes the statements contained in the notice regarding confidentiality of the identity of callers and prohibitions against retaliation are adequate to overcome the understandable reluctance a sincere potential complainant may have.

Finally, although the statement is correct, the Department adopts the suggestion that the reference to violations of state criminal and civil laws be deleted because it is unnecessary and potentially inflammatory.

C. RESPONSIBILITIES OF CHILD PROTECTIVE SERVICES AGENCIES

A number of commenters addressed the provision of the proposed rule requiring that state child protective services agencies establish and maintain written methods of administration and procedures to ensure full utilization of their au-

thorities pursuant to state law to prevent instances of medical neglect of handicapped infants.

Several child protective services agencies and their respresentatives opposed this provision. As stated by the National Council of State Public Welfare Administrators:

> While the NCSPWA agrees there is a need to establish additional protections for infants born with handicapping conditions, * * * we believe the child protective services agency is not, as a rule, the appropriate authority to establish standards for medical treatment, to police the medical profession, or to make the kinds of medical/ethical judgments required in this area.

The State of Nebraska Department of Public Welfare expressed support for increased involvement of state child protective services agencies:

> We feel that the agency with primary responsibility for investigation and enforcement of this law should be the State Protective Services Agency. We further would suggest that hospital administration be charged with the responsibility for reporting any possible violations of this law to the State Protective Services Agency.* * * The State Protective Services Agency should be responsible for reporting to the Office of Civil Rights the results of any actions taken as a result of the report.* * *

Some commenters urged deletion of the requirement that state agencies report cases to OCR because it conflicts with the confidentiality requirements of state child abuse and neglect statutes and presents an unnecessary administrative burden. Other commenters suggested that this requirement be expanded to require reports to OCR at each step of an agency's investigation. Other commenters suggested that state child protective services agencies be required to involve state protection and advocacy systems for the developmentally disabled in all of its activities related to this issue.

Response

Section G, below, includes a discussion of the applicability of section 504 in cases where a refusal to provide medically beneficial treatment is a result, not of decisions by a health

care provider, but of decisions by parents. As explained in that section, it is the responsibility of the hospital in such a case to report the circumstances to the state child protective services agency. If that agency receives Federal financial assistance in its child protective services program, it may not fail, solely on the basis of the infant's present or anticipated physical or mental impairments, to utilize its full authority pursuant to state law to protect the infant. Although there are some variations among state child protective statutes, all have the following basic elements: a requirement that health care providers report suspected cases of child abuse or neglect, including medical neglect; a mechanism for timely receipt of such reports; a process for administrative inquiry and investigation to determine the facts; and the authority and responsibility to seek an appropriate court order to remedy the apparent abuse and neglect, if it is found to exist.

Consistent with the applicability of section 504 to child protective services agencies and with the typical elements of state child protective statutes, the proposed rule included a subsection requiring that, within 60 days of the effective date, "each recipient state child protective services agency shall establish and maintain written methods of administration and procedures to assure that the agency utilizes its full authority pursuant to state law to prevent instances of medical neglect of handicapped infants."

This provision was modeled after an existing provision in the Department's regulation implementing title VI of the Civil Rights Act of 1964, 45 CFR 80.4(b), which requires all continuing state programs to have "such methods of administration for the program as are found by the responsible department official to give reasonable assurance" of compliance.

The proposed rule went on to specify several elements which must be included in the agency's methods of administration and procedures. Four of these elements precisely mirror the common fundamental components of state child protective statutes.

The proposed rule also called for immediate notification to the Department of each report of suspected medical neglect of a handicapped infant, the steps taken by the agency to in-

vestigate such report, and the agency's final disposition of such report. This requirement was also based upon an existing regulation, 45 CFR 80.6(b), which requires compliance reports "in such form and containing such information" as the Department may require. Therefore, the proposed rule's requirement for notification to OCR is simply a specification of a type of compliance report the Department deems necessary to monitor the recipient's compliance.

With respect to the comments concerning the potential conflict between this notification requirement and the confidentiality provisions of state child abuse and neglect statutes, this provision is entirely consistent with existing regulatory requirements of recipient child protective services agencies under 45 CFR 80.6(c), which includes the statement: "Asserted considerations of privacy or confidentiality may not operate to bar the Department from evaluating or seeking to enforce compliance with this part."

In addition, HHS regulations requiring, as a condition of receiving Federal funds, state child protective services agencies to protect the confidentiality of child abuse and neglect information also make clear that HHS and the Comptroller General of the United States must have access to documents and other records "pertinent to the HHS grant." 45 CFR 1340.14, 74.24.

The Department has not adopted the suggestion that more detailed requirements be established for state child protective services agencies because the requirements should be flexible enough to be easily incorporated into existing agency procedures.

Section 84.55(c)(1) of the final rules adopts the corresponding provision of the proposed rules without substantive change. In summary, it simply restates existing section 504 responsibilities of recipient state child protective services agencies; requires standard procedures to assure compliance (as has been long required for continuing state programs under title VI); specifies the basic elements of those procedures (which precisely mirror the standard components of state statutes); and specifies a form of compliance reports required under existing agency responsibilities. Consistent with the Department's investigative guidelines, § 84.55(c)(2) encour-

ages state agencies to involve Infant Care Review Committees in connection with the agencies' actions pursuant to its state law and procedures.

D. EXPEDITED ACCESS TO RECORDS

The final rules create a limited exception to the Department's existing regulations pertaining to access to sources of information. The existing regulation, 45 CFR 80.6(c), made applicable to section 504 cases by 45 CFR 84.61, states:

> Each recipient shall permit access by the responsible Department official or his designees during *normal business hours* to such of its books, records, accounts, and other sources of information, and its facilities as may be pertinent to ascertain compliance with this part. [Emphasis supplied.]

The proposed rules included a modification to specify that access to pertinent records and facilities of a recipient "shall not be limited to normal business hours when, in the judgment of the responsible Department official, immediate access is necessary to protect the life or health of a handicapped individual." The final rules adopt this change in § 84.55(d).

A number of commenters expressed support for the provision as essential to efforts to save lives. Others objected on the grounds that investigations are highly disruptive, the OCR officials are not qualified to make a judgment regarding the degree of danger to the life or health of a handicapped individual and that the rule should specify circumstances warranting access and procedures applicable to investigations after normal business hours.

Response

The Department views this as a minor, technical clarification. Access to recipient facilities and sources of information is required by existing regulations and is essential for the Department to carry out its statutory obligation to determine whether recipients are in compliance with civil rights laws. The provision in existing regulations regarding "normal business hours" is nothing more than a recognition that many recipients conduct their federally assisted programs and activities only during those hours.

The furnishing of inpatient medical services, however, is not a 9:00 a.m. to 5:00 p.m., Monday through Friday undertaking. Rather, the "normal business hours" for nurseries and neonatal intensive care units are 24 hours a day, seven days a week. The Department, therefore, has the authority to seek pertinent records at any time even in the absence of revision. Nonetheless, the Department adopts this change to clarify its authority and recipients' obligations. The objections expressed regarding this provision are substantially the same as objections to investigative procedures generally, and are discussed in section H, below.

This modification makes clear where the circumstances indicate a risk of imminent, irrevocable harm due to suspected noncompliance, the Department will, as it must, initiate immediate action to determine compliance.

E. EXPEDITED ACTION TO EFFECT COMPLIANCE

The final rules include a slight revision to existing regulatory procedures concerning remedies for noncompliance. Existing regulations, 45 CFR 80.8(a) and (d) (made applicable to section 504 cases by 45 CFR 84.61), provide:

> If there appears to be a failure or a threatened failure to comply with this regulation ... compliance with this part may be effected by the suspension or termination of or refusal to grant or to continue Federal financial assistance or by any other means authorized by law. Such other means may include ... a reference to the Department of Justice with a recommendation that appropriate proceedings be brought to enforce any rights of the United States under any law of the United States ... or any assurance or other contractual undertaking....
>
> * * * * *
>
> No action to effect compliance by any other means authorized by law shall be taken until (1) the responsible Department official has determined compliance cannot be secured by voluntary means, (2) the recipient or other person has been notified of its failure to comply and of the action to be taken to effect compliance, and (3) the expiration of at least 10 days from the mailing of such notice to the recipient or other person.

The proposed rule included a provision that the normal requirement of providing 10-days notice "shall not apply when,

in the judgment of the responsible Department official, immediate remedial action is necessary to protect the life or health of a handicapped individual." The final rule, in § 84.55(e), adopts this revision.

A number of commenters expressed support for this provision as essential to efforts to save lives; others objected because the rule did not identify standards for waiving the 10-day notice or alternate procedure to be followed.

Response

The Department considers this a minor, technical change. The 10-day notice was designed to facilitate pursuit of informal compliance in circumstances where noncompliance did not imminently threaten lives. The failure to provide nourishment or treatment to a handicapped infant, however, may have such a consequence.

As a matter of legal interpretation, the Department believes the normal 10-day notice rule would, even absent the proposed change, be inapplicable in a case where the government seeks a temporary restraining order to sustain the life of a handicapped infant in imminent danger of death. Such actions would often be for the purpose of preserving the status quo, such as by continuing the provision of nourishment and routine care, pending a more definitive determination of compliance or noncompliance with section 504, rather than "to effect compliance" following a determination of noncompliance. In addition, the Department believes federal judges would be appropriately loathe to allow minor procedural technicalities to defeat totally the accomplishment of the statutory purpose. Nonetheless, the Department proposed this limited exception to the normal 10-day notice rule to clarify its authorities and corresponding recipient responsibilities.

The determination of the need to waive the 10-day notice will be made in accordance with the standard investigative procedures, explained in section H, below. Concerning alternate notice procedures, the final rule provides that oral or written notice will be provided as soon as practicable.

F. GUIDELINES RELATING TO HEALTH CARE FOR HANDICAPPED INFANTS

Most of the comments submitted during the comment period dealt with issues well beyond the specific provisions of the proposed rules, such as the applicability of section 504 to this subject matter and the Department's section 504 enforcement process.

Like the proposed rules, the final rules contain four discrete requirements applicable to recipients of Federal financial assistance. First, hospitals must post an informational notice. Second, the normal 10-day notice before initiating action to effect compliance can be waived when immediate action is necessary. Third, access by the Department to pertinent records and facilities can be obtained after "normal business hours" when immediate access [is] necessary. Fourth, state child protective services agencies must establish procedures to utilize their full authority under state law to prevent medical neglect of handicapped infants.

To bring these specific provisions further back into focus, it is useful to note what the final rules, like the proposed rules, do *not* do. They do not establish the applicability of section 504 to the provision of health care to handicapped infants. The applicability of section 504 is already established by the statute and the existing HHS regulations. They do not establish the authority or procedures of HHS to investigate reports of suspected noncompliance with section 504. Authority and procedures are already established by the statute, existing regulations and administrative practices. They do not establish a toll-free telephone number, which has been established and is in operation. Although most of the controversy concerning the rules relates to the broader issues, the mandatory aspects of the final rules deal only with several discrete points.

Nonetheless, many of the comments relating to the broader issues were highly relevant and valuable. Other comments on the broader issues reflected a lack of understanding of how the Department interprets the applicability of section 504 in this area and the Department's compliance procedures. To clarify these issues, the final rules include an appendix, which sets forth guidelines relating to health care

for handicapped infants. This appendix includes interpretative guidelines relating to the applicability of section 504 and guidelines for HHS investigations in this area. These guidelines do not independently establish rules of conduct or substantive rights and responsibilities, which are established by the statute and existing regulations. The Department will apply these guidelines flexibly to take into account the circumstances presented in each case regarding both the determination of compliance or noncompliance and the conduct of the investigation. These guidelines are set forth as an appendix to the final rules simply to assist recipients and the public in understanding the Department's general interpretations and procedures. This appendix becomes a part of the permanent Code of Federal Regulations.

G. INTERPRETATIVE GUIDELINES RELATING TO THE APPLICABILITY OF SECTION 504

Medically Beneficial Treatment

As stated in the preamble to the proposed rules, the Department interprets section 504 as requiring that medically beneficial treatment not be withheld, solely on the basis of handicap, from a handicapped infant.

Three of the questions on which the July 5 notice of proposed rulemaking specifically solicited comments concerned the issue of medically beneficial treatment as the standard to guide treatment decisions, including further explanations that would assist health care providers and the public in understanding the requirements of section 504, implications concerning cost and the allocation of medical resources, and the impact of perceived economic, emotional and marital effects on parents.

Among commenters supporting the standard of providing medically beneficial treatment was the Down's Syndrome Congress:

> Some children may be unwanted by their parents.... The Down's Syndrome Congress does not seek to judge those parents who do not feel that they can adequately parent because of the handicap. Rather, we seek to make available those adoption homes that want children who have Down's syndrome.

Also typical of comments in support of the standard of providing medically beneficial treatment was the comment of the Association for Retarded Citizens:

> No quality of life or other such considerations are acceptable to the ARC. Although we are primarily a parent organization and many ARC members have had significant difficulty (financial, emotional, etc.) raising their mentally retarded child, we come down strongly on the side of the child.
>
> Available medical and other technology is not able to fully predict the future capacity of most mentally retarded children, especially in the first days and weeks of life. Our members can cite numerous examples of improper and wrong advice given to them by physicians about the future capacities of their children.

A number of commenters argued that the medically beneficial treatment standard is inappropriate. For example, the Department received the following comment from a Texas physician:

> [N]ot only is the "very strict standard" advocated by the President's Commission "not being uniformly followed," [as stated in the HHS July 5 NPRM] it is probably close to *uniformly not* being followed. The "very strict standard" the Secretary of Health and Human Services is trying to foist on the medical community is contrary to the usual practices of that community. (Emphasis in original.)

Similarly, the following comment was submitted by an Alabama physician:

> Recently I have treated a 13-month old black child who has congenital heart disease, spastic encephalopathy, vomiting, repeated bouts of bilateral pneumonia, internal squint of the left eye, and mental deficiency. He is one of the thousands of children who are the victims of the neonatal intensive care units located in every medical center. He was born premature, weighing two pounds and ten ounces. With modern treatment and instruments he survived. These children have no future and are a terrible burden on their parents and this nation.
>
> * * * What good is it treating these premature babies? Will it not be better if they are left to die? * * *

> We are compounding our problems by bringing into life thousands of congentially sick babies which nature has rejected.

A number of commenters, particularly medical organizations, suggested different articulations of standards. For example, the American Medical Association combines a number of notions in articulating the standard to be applied, including consideration of "quality of life", and deference to parental decisions unless there is "convincing evidence to the contrary." The full text of the AMA position is as follows:

> QUALITY OF LIFE. In the making of decisions for the treatment of seriously deformed newborns or persons who are severely deteriorated victims of injury, illness or advanced age, the primary consideration should be what is best for the individual patient and not the avoidance of a burden to the family or to society. Quality of life is a factor to be considered in determining what is best for the individual. Life should be cherished despite disabilities and handicaps, except when prolongation would be inhumane and unconscionable. Under these circumstances, withholding or removing life supporting means is ethical provided that the normal care given an individual who is ill is not discontinued. In desperate situations involving newborns, the advice and judgment of the physician should be readily available, but the decision whether to exert maximal efforts to sustain life should be the choice of the parents. The parents should be told the options, expected benefits, risks and limits of any proposed care; how the potential for human relationships is affected by the infant's condition; and relevant information and answers to their questions. The presumption is that the love which parents usually have for their children will be dominant in the decisions which they make in determining what is in the best interest of their children. It is to be expected that parents will act unselfishly, particularly where life itself is at stake. Unless there is convincing evidence to the contrary, parental authority should be respected.

Another articulation of standards, submitted by the Biomedical Ethics Committee of the University of Minnesota Hospitals, includes the following ethical principles:

> When the burden of treatment lacks compensating benefit or treatment is futile, the parent(s) and attending physician need not continue or pursue it.
>
> Therapies lack compensating benefit when: (a) they serve merely to prolong the dying process; (b) the infant suffers from intolerable, intractable pain, which cannot be alleviated by medical treatment; (c) the infant will be unable to participate even minimally in human experience.

Probably the most poignant comments regarding the standard which should be applied relating to the provision of medical care to handicapped infants were submitted by parents of handicapped children. Of 100 commenters who identified themselves as parents of handicapped persons, 95 supported the proposed rule and five opposed it. From a Montana mother:

> My daughter Keough was born in November 1980 with Down's syndrome and a host of birth defects in her digestive system similar to Baby Doe's problems * * * Twenty minutes after her birth our then pediatrician offered to let her starve in the hospital nursery* * *
>
> * * * * *
>
> * * * There are times when I am getting up for the tenth time during the night to suction my daughter's trach tube so she can breathe that I would give anything not to have to deal with the situation, but I will never regret having her as part of the family.

From a mother and father, both physicians, in California:

> [A]s the parents of an eight-year-old boy with Down's Syndrome, who suffers from marked retardation and a severe cardiopulmonary condition, we do appreciate both the deep anguish and the countless joys that derive from caring for and caring about a severely handicapped child. There is no limit set on the strength, the growth and the fulfillment that his love continues to bring us every day. For his sake and for the sake of all the handicapped newborn, it is urgent that safeguards be enacted. Let merciful caring, not mercy-killing, be our answer to their needs.

Another dimension of the comments concerning the interpretation of section 504 as requiring that medically beneficial treatment not be withheld solely on the basis of handicap re-

lates to the difficulty of determining the "medically beneficial treatment." As stated by the Children's Hospital of Boston:

> [The NPRM] states that the denial of treatment where there is no medical benefit to the individual would not be discriminatory because the individual would not be a "qualified handicapped person" within the meaning of section 504. [A problem with this analysis is that] it relies on outcome which cannot always be predicted or, even if predicted is not always accurate, may be affected by other factors, and may not even be known for an indeterminate time. If section 504 is to provide guidance in treatment situations, its applicability should be known at the outset. Otherwise staff will be subject to an after-the-fact scrutiny which may well be inaccurate and oppressive.

Another comment regarding the role of medical judgments was submitted by presiding Judge John G. Baker, Monroe Superior Court, Division III, the Judge who decided the Bloomingtom Infant Doe case:

> The question in the Infant Doe case was, when parents are confronted with two competent medical opinions, one suggesting that corrective surgery may be appropriate and the other suggesting that corrective surgery and extraordinary measures would only be futile acts, does the law allow the parents to select which medical course to follow? It was the decision of the Indiana Court that the law provided the parents with the responsibility of choosing which medical course to follow without governmental intervention.

Response

The Department's position remains unchanged. Section 504 provides:

> No otherwise qualified handicapped individual shall, solely by reason of his handicap, be excluded from participation, be denied the benefits of, or be subject to discrimination under any program or activity receiving Federal financial assistance...

The statute defines a "handicapped individual" as:

> Any person who (i) has a physical or mental impairment which substantially limits one or more of such person's major life activities ... or (iii) is regarded as having such an impairment.

A key issue in applying section 504 in any context is that the handicapped individual who is allegedly excluded from participation in, denied the benefits of, or subject to discrimination under a federally assisted program or activity be "otherwise qualified" to participate in, or benefit from, the program or activity, in spite of his or her handicap. In the context of receiving medical care, the ability to benefit for a handicapped person is the ability to benefit medically from treatment or services. If the handicapped person is able to benefit medically from the treatment or service, in spite of the person's present or anticipated physical or mental impairments, the individual is "otherwise qualified" to receive that treatment or service, and it may not be denied solely on the basis of the handicap.

Therefore, the analytical framework under the statute for applying section 504 in the context of health care for handicapped infants is that health care providers may not, solely on the basis of present or anticipated physical or mental impairment of an infant, withhold treatment or nourishment from the infant who, in spite of such impairments, will medically benefit from the treatment or nourishment.

Not only is this analytical framework directed by the statute, the Department believes the medically beneficial treatment standard is the appropriate guiding principle for providing health care services to handicapped infants. The Department agrees with the President's Commission that "it is all too easy to undervalue the lives of handicapped infants," and that it is "imperative to counteract this" by excluding "consideration of the negative effects of an impaired child's life on other persons" and to treat handicapped infants "no less vigorously than their healthy peers."

The Department also agrees with the essential principle contained in the joint statement of November 29, 1983, by the coalition of medical groups and the disability organizations, including the American Academy of Pediatrics, the National Association of Children's Hospitals and Related Institutions, the association for Retarded Citizens, the Spina Bifida Association of America, and others:

> When medical care is clearly beneficial, it should always be provided.... The individual's medical condition should be the sole focus of the decision.

Consistent with the recommendations of the President's Commission and the principles agreed to by the coalition of medical and disability groups, paragraphs (1), (2) and (3) of section (a) of the appendix state the basic interpretative guidelines of the Department for applying section 504 in this context. These interpretative guidelines make clear that health care providers may not, solely on the basis of present or anticipated physical or mental impairments of an infant, withhold treatment or nourishment from the infant, who, in spite of such impairments, will medically benefit from the treatment or nourishment. They also made clear that futile treatments or treatments that will do no more than than temporarily prolong the act of dying of a terminally ill infant are not required by section 504, and that, in determining whether certain possible treatments will be medically beneficial to an infant, reasonable medical judgments in selecting among alternative courses of treatment will be respected. The principle of respecting reasonable medical judgments reflects the Department's recognition that in many cases the process of medical decisionmaking is not mechanical and precise. Analyses of medical risks, medical benefits, possible outcomes, complications, and the like require experience and judgments. Most of all, they must be specifically based on the actual circumstances presented in any given case. The statutory framework does not provide for, nor will the Department seek to engage in, second-guessing of reasonable medical judgments regarding medically beneficial care.

The principle of respecting reasonable medical judgments in the context of applying section 504 is also consistent with analogous case law. For example, the Supreme Court has made it clear that the application of constitutional protections do not interfere with *bona fide* medical judgments so as to authorize a court "to specify which of several professionally acceptable [treatment] choices should have been made." *Youngberg* v. *Romeo*, 457 U.S. 307, 321 (1982).

However, the Department also recognizes that not every opinion expressed by a doctor automatically qualifies as a reasonable medical judgment. For example, a doctor's opinion that available corrective surgery to save the life of a Down's syndrome infant should be withheld is contrary to

the opinion of the President's Commission and comments submitted to the Department by the American Academy of Pediatrics, the National Association of Children's Hospitals and Related Institutions, and other medical organizations. It is not within the bounds of reasonable medical judgment and is not entitled to deference.

Parental Decisions

A number of commenters argued that the Department's analysis of section 504's applicability fails to take into account the lack of authority hospitals and physicians have to perform treatment to which the parents have not consented. Some commenters expressed a belief that the Department purports to require physicians and hospitals unilaterally to overrule parental decisions. As stated by the American Medical Association:

> If section 504 is applied as the Department claims it should be, physicians and hospitals will be required to treat a handicapped infant in all cases, regardless of parental consent, for fear of sanctions allegedly authorized by section 504.

Similarly, the National Association of Children's Hospitals and Related Institutions stated:

> Nor does the rule recognize that, in lieu of indications to the contrary, decisions of care of the infant made by these parents, based on their determination of the child's best interest, are theirs to make, a right and responsibility assigned to them universally by state statute....

Also in connection with the issue of a recipient's section 504 responsibilities in cases where parents refuse to consent to medically beneficial treatment, a number of commenters criticized a statement included in the Department's May 18 notice to health care providers that:

> Health Care providers should not aid a decision by the infant's parents or guardian to withhold treatment or nourishment discriminatorily by allowing the infant to remain in the institution.

The criticism was that to discharge the infant, as the statement implied the hospital should do, would be unlikely to ad-

vance the objective of assuring that the infant receive medically beneficial treatment.

Response

The Department's position has been, and continues to be, that the lack of parental consent does have an impact on a recipient hospital's section 504 responsibilities, but that the lack of parental consent to provide particular treatment does not remove from hospitals the obligation to operate other aspects of their program without discrimination.

Although the need may not arise frequently, it is an accepted part of the operation of hospitals to contest the denial of parental consent when such a decision is not in the best interest of a child. Most hospitals have established procedures to petition courts to order medical care when parents do not provide consent for treatment that is medically needed and appropriate.

In addition to the internal hospital procedures, state laws generally establish responsibilities of health care professionals where treatment is being withheld because of improper denial of parental consent. Health care professionals are generally required by state law to report cases of abuse, neglect, or other threats to a child's health. These laws, whether explicitly or implicitly, include the denial of needed medical treatment as an event requiring reporting.

The requirement that health care providers report instances of improper denial of medical care is no less a part of their program than is the provision of care itself. Both arise from the recipients' program of administering to the medical interests of its patients. Section 504 prohibits discrimination on the basis of handicap in the operation of federally assisted programs and activities. Thus, a recipient that, as a matter of practice or law, reports to State authorities the withholding of needed medical treatment from an infant may not deny the same service or benefit to a qualified handicapped infant because the infant is handicapped.

Section 504 applies only to programs or activities receiving federal financial assistance; it does not apply to decisions made by parents. Where a nontreatment decision, no matter how discriminatory, is made by parents, rather than by the

hospital, section 504 does not mandate that the hospital unilaterally overrule the parental decision and provide treatment notwithstanding the lack of consent. But it does require that recipient hospitals not fail, on the basis of handicap, to report the apparently improper parental decision to the appropriate State authorities, or to seek judicial review itself, so as to trigger the system provided by State law to determine whether the parental decision should be honored. Action by hospitals to seek judicial review is not uncommon in cases where, for example, parents have objected on religious grounds to a medically necessary blood transfusion for their child.

The Department agrees with the criticism of the sentence in the May 18, 1982 notice. This statement reflected a recognition by the Department that section 504 does not require hospitals unilaterally to overrule parental decisions, and that hospitals cannot provide treatment without parental consent. The point should have been better stated that a recipient hospital may not blindly implement improper and discriminatory parental decisions. Rather, the hospital should resort to the system provided by state law to determine whether a parental decision should be implemented.

Therefore, the proper analysis of the applicability of section 504 in cases where the failure to provide medically indicated treatment is due to a lack of parental consent is that a recipient hospital is not required to seek to unilaterally overrule the parents, but it must adhere to the standard practice, as required by state law, to make a report to the state agency charged under state law with responsibility to initiate the determination as to whether the parental decision was proper, or to seek judicial review itself. This interpretative guideline is set forth in section (a)(4) of the appendix.

Rather than representing an improper Federal government attempt to "question and overturn the decisions of parents concerning their children's medical treatment," the Department is simply requiring that the long-standing requirements and mechanisms of *state* law for defining the limits of parental authority not be rendered, through discriminatory actions of recipient hospitals, *de facto* inoperative.

Examples

The July 5 proposed rule was accompanied by an appendix explaining the manner is which section 504 applies to the provision of health care services to handicapped infants and providing several examples of its applicability to particular factual situations. A number of commenters criticized statements contained in that appendix. Criticisms and comments were as follows: (a) Use of phrases such as "futile therapies", "services generally provided", and "dubious medical benefit" are ambiguous. (b) The characterization of infants with intracranial hemorrhage as analogous to anencephaly is incorrect. Intracranial hemorrhages vary greatly in severity, and are generally treatable and treated. (c) The American Society for Parenteral and Enteral Nutrition stated that although there are no circumstances justifying "withholding oral feeding through a working digestive tract in any patient capable of digesting food, in whole or in part," there may be "limited circumstances" in which not providing nourishment through intravenous means "may be appropriate." (d) The appendix does not indicate the appropriate care for infants who have conditions with prognoses worse than Down's syndrome but less severe than anencephaly, such as Trisomy 18, Trisomy 13, Holoprosencephaly, Hydranencephaly, Cornelia de Lange Syndrome, and many others.

(e) "It would be impossible to develop a complete list be handicaps to which the regulations apply. The limited ability to predict outcomes, and the rapid changes in diagnostic and therapeutic modalities make such a goal wholly impracticable."

Response

The application of constitutional and statutory civil rights protections in scores of contexts is difficult. A glance at the Supreme Court's docket confirms this, as every year difficult issues are presented to the Court for resolution. These cases often produce split decisions and multiple opinions.

Therefore, it is to be expected the definitive statements on various dimensions of the applicability of the handicapped discrimination law in connection with health care for handicapped infants, a subject no less difficult than many other as-

pects of civil rights law, would be few. The imprudence of seeking to speculate on the outcome of applying section 504 in a wide variety of specific factual circumstances was underscored by some of the comments received.

Keeping in mind the utility of providing some examples to assist in understanding the analytical framework of the statute, but also the need to allow individualized attention to specific factual circumstances, the guidelines included in the appendix (section (a)(5)) set forth examples dealing with Down's syndrome, spina bifida, anencephaly, and extreme prematurity.

The Department agrees with the comment that it would be impossible to establish a specific list of all handicapping conditions and the proper treatment in each case. None of the commenters who perceived ambiguities had convincing answers to the questions they raised.

It is appropriate that the law (and thus the government) does not prospectively and unequivocally answer every hypothetical question. In many cases, the law, like medical treatment, can only be applied on a case-by-case basis with a full appreciation for the facts presented.

But it is also appropriate that the law and government have an analytical framework for approaching the issue and a procedural framework for seeking, in cooperation with the medical community and advocacy groups, to narrow the "gray area." The final rules seek to do no more, and importantly, no less.

H. GUIDELINES FOR HHS INVESTIGATIONS RELATING TO HEALTH CARE FOR HANDICAPPED INFANTS

Conduct of Investigations

The July 5 notice of proposed rulemaking solicited comments on HHS investigative procedures. A number of commenters argued that OCR complaint investigations are highly disruptive. The primary concerns expressed in this regard were:

(a) Due to the complexity of the subject matter, there are many erroneous complaints, either by well-intentioned, but ill-informed, persons or by disgruntled employees.

(b) Anonymous calls are not reliable.

(c) Investigations monopolize the time of physicians, nurses and other hospital staff, and make medical records, while under review by OCR investigators, unavailable.

(d) Investigations carry with them the potential for sensational media coverage, which can unjustly damage the good reputations of parents, hospitals and health care professionals.

(e) The presence of OCR investigators is likely to frighten other infants' parents who will assume that, because investigators are present, the hospital must be guilty of improper conduct.

Response

Although some potential for inconvenience or disruption exists in connection with any type of law enforcement investigation, because of the traumatic circumstances of an infant's illness, the potential for sensationalistic media coverage, and other factors, the Department is very sensitive to the special nature of "Infant Doe" investigations. As HHS has gained experience in conducting these investigations, revisions to investigative procedures have been implemented to minimize any disruptive effects. It is the policy of the Department to do everything possible, consistent with its statutory obligation to investigate effectively all complaints of violations of section 504, to minimize any disruptions that may be caused by OCR investigations.

OCR has made adjustments to investigative procedures. It now undertakes a careful screening of complaints in an effort to avoid unnecessary on-site investigations. This screening consists of immediately initiating a preliminary inquiry with the hospital to obtain information regarding the infant in question. The information initially received from the complainant and that received from the hospital is then evaluated to determine whether there is a need for an on-site investigation. Particular factors taken into account are the source of the complainant's information (first-hand knowledge, overheard a discussion, etc.), the complainant's position to have reliable information (a nurse in the ward where the infant is being treated, a friend of a friend, etc.), the specificity of the information provided by the complain-

ant and hospital, whether there is any indication of a lack of parental consent for the provision of all medically beneficial treatment, the analysis of the ICRC, whether the hospital is cooperative in connection with the inquiry, and other pertinent factors.

None of these factors considered in evaluating the information provided by the complainant and the hospital is, by itself, determinative. For example, the Department prefers that the complainant provide his or her name. Not only does it corroborate that the complainant takes the matter seriously and reflects some degree of confidence the complainant has in the accuracy of the information being conveyed, having the complainant's name also permits follow-up communications to seek clarification of the information gathered. However, the Department recognizes that a complainant may not be willing to provide his or her name due to fear of retaliation, and the anonymity does not necessarily suggest that the complaint is not valid, particularly if the specificity of the information provided and other factors support the credibility of the complaint. Therefore, the determination as to whether an on-site investigation is needed is made on the totality of the information available to OCR from the complainant, the hospital, and any other source consulted (such as an OCR medical consultant and the state child protective services agency).

HHS believes this procedure, if hospitals cooperate in its implementation, can avoid unnecessary on-site investigations, which inherently have a potential for some inconvenience. Although hospital officials may be properly reluctant to provide information over the telephone, they can confirm the credentials of the OCR investigator making the telephone contact by calling the toll-free telephone number to verify that the caller is, in fact, an OCR investigator.

Where, as a result of this preliminary inquiry, there appears to be no need for an immediate on-site investigation, none will be conducted. However, to assure that HHS is adequately meeting its statutory responsibility, where there is a significant question as to compliance with section 504, doubt will be resolved in favor of initiating an on-site investigation.

This preliminary inquiry process is undertaken by OCR in an effort to accommodate the special circumstances presented in connection with "Infant Doe" complaints. This procedure should not be construed as suggesting that the Department believes there are any limitations to its legal authority to investigate all complaints or to otherwise collect information regarding recipient compliance in accordance with the Department's existing section 504 regulations. Nor does this preliminary inquiry process establish any legally enforceable procedural right or precondition to the conduct of on-site investigations.

When on-site investigations are conducted, OCR's procedures minimize any potential inconvenience or disruption. Every effort is made, consistent with the need to obtain prompt information, to accommodate the busy schedules of health care professionals to avoid diverting them from their important duties. Similarly, OCR has never had a problem working out access to medical records to avoid their being unavailable to health care professionals who also need access to them.

With respect to media interest, OCR has a firm policy of providing no comment to the press on the details of any open investigation. HHS believes organizations or individual complainants concerned about proper patient care should be extremely sensitive to threats to proper care inherent in making premature and unsupported comments to the media. Similarly, the media should be attentive to OCR's admonition, regularly given in response to media questions, that the fact that an investigation is being conducted does not imply that an allegation is true.

Section (b)(1) through (5) of the appendix spell out the basic guidelines, including the preliminary inquiry process, applicable to HHS investigations in this area. These guidelines make specific reference to the role of Infant Care Review Committees. Whenever a hospital has an ICRC, established and operated substantially in accordance with the suggested model, the Department will consult closely with the ICRC in connection with a preliminary inquiry or investigation and will give careful consideration to the analysis and recommendations of the ICRC.

The Department believes OCR procedures, including the initial inquiry process, minimize the potential for disruption. HHS will, on the basis of further experience gained, such as with ICRCS, continue to evaluate its procedures consistent with the policy of effective enforcement with a minimum of disruption. The Department also notes that there is probably an irreducible level of inconvenience associated with any effort to provide safeguards to prevent the fatal consequences of discriminatory decisions. It must be recognized, however, that the risks of a certain amount of inconvenience or disruption are significantly preferable to the risks of tragic loss of life due to discriminatory decisionmaking.

Use of Medical Consultants

Another concern expressed by commenters relates to the qualifications of the individuals involved in the administrative fact finding process to evaluate correctly the medical circumstances present in any particular case. For example:

> The Alabama Hospital Association strongly feels that the [investigative] team should be comprised of highly trained and licensed medical personnel. Under no circumstances should anyone less than licensed medical personnel be allowed to intrude in this area of medical decisionmaking and impose alternative judgments or conclusions.

The Spina Bifida Association of America made a similar comment from a different perspective:

> The key to effective enforcement is securing an independent medical examination of children allegedly being denied treatment, by a physician or medical team both skilled in modern treatment techniques *and* committed to the equal treatment principle. Such physicians do exist, particularly at expertise centers that have specialized in the care of children with spina bifida. The only way to ensure effective enforcement is to give disability rights groups like SBAA the ability to recommend *which* expertise centers and expert consultants are used by the regional OCR offices to conduct the independent medical examinations.

Response

HHS agrees that OCR investigators do not have the medical expertise to make independent judgments concerning difficult medical issues. For this reason, the Office for Civil Rights has made arrangements with qualified physicians to serve as medical consultants to OCR in "Infant Doe" investigations. This process is noted in section (b)(6) of the appendix.

The role of the OCR medical consultants is to provide OCR with an analysis of the medical issues present in any particular case, and an opinion as to whether medically beneficial treatment was provided. Based on this analysis, OCR makes a determination as to whether any medically beneficial treatment may have been discriminatorily denied solely on the basis of the infant's handicap.

The extent of the involvement of the OCR medical consultant has varied depending upon the circumstances of particular cases. In all cases the OCR medical consultant reviews the pertinent medical records. In some cases the OCR medical consultant and the attending physician have discussed a case by telephone. HHS believes the experience to date with OCR medical consultants demonstrates the effectiveness of their involvement. HHS is aware of no case in which a recipient has challenged the quality of the medical consultant's evaluation or the OCR findings based upon it.

It is important that all interested groups understand the precise and limited role of the OCR medical consultants. Their function is *not* to take over the medical management of particular cases, to conduct a personal, independent examination of the infant, to make independent treatment recommendations to parents, or to otherwise engage in any direct practice of medicine concerning the infant.

The Department has no authority to compel unilaterally an independent medical examination of a child who is the subject of a section 504 complaint. Under applicable requirements of law, physicians may not practice medicine on an infant patient without the consent of the parents or an order of a court of competent jurisdiction.

In any given case, any of a wide variety of circumstances may be present regarding the actions of parents and health care providers. Regardless of the circumstances, the first step is to determine the facts. Only if the facts demonstrate that there is a need for governmental action can that action be pursued. A court will only issue an order if there is a showing of a need for the order, such as evidence that the hospital *is* out of compliance with section 504 or showing that the parents *are* medically neglecting the infant. Such a showing cannot be made on the basis of the bare allegations of a complaint or without a determination of the facts.

OCR's function in an investigation is to determine the facts, and the function of the medical consultant is to assist OCR in this effort. The process of determining the facts typically involves a review of medical records and discussions with health care providers involved. The OCR medical consultants assist in this process by providing identification and expert analysis of the medical issues involved. These consultants do not, and may not under applicable law, take over the medical management of the case.

With respect to the suggestion that HHS give disability groups the opportunity to recommend qualified physicians to serve as OCR medical consultants, the Department would welcome such suggestions from all interested groups.

The Department is unable to commit itself to having a medical consultant participate in person in every on-site investigation. However, the guidelines contained in the appendix state that, to the extent practicable, the OCR medical consultant will discuss the case with the hospital's ICRC or appropriate medical personnel by telephone.

Prompt Report of Investigative Findings

Another complaint made by a number of commenters regarding OCR enforcement procedures concerns the sometimes lengthy delay between completion of the on-site investigation and receipt by the hospital of notification of the outcome of the investigation. Commenters expressed concern that, particularly in connection with investigations that may have attracted local media attention, where the OCR investigation found no evidence of a violation, the hospital

should have the ability to reassure the public promptly that it was involved in no improper activity.

Response

The point is well taken. Office for Civil Rights procedures pertaining to all investigations require that before the office makes an official finding, whether it is of compliance or noncompliance, a thorough record is complied and reviewed by supervisory officials. Experience in connection with "Infant Doe" cases is that formal findings have been made in less time than is typical in connection with other civil rights investigations. However, there is generally a need for careful review by an OCR medical consultant, an HHS attorney, and supervisory officials.

The Department recognizes that there are special circumstances in connection with Infant Doe cases, and is instituting a special notification to recipient hospitals in cases where an emergency on-site investigation has been conducted. As a matter of practice, on-site investigation of complaints alleging that an infant's life is in peril due to the discriminatory withholding of medically beneficial care are conducted immediately for the primary purpose of determining whether there is a need to ask the Department of Justice to seek immediate injunctive relief to compel compliance with section 504. Generally, during the course of the investigation, when sufficient information has been obtained and discussed with the OCR medical consultant, a decision is made on whether there is such a need.

The new procedure is that, when a decision is made that there is no need to make an immediate referral to the Justice Department, the recipient hospital will be immediately notified of that decision. The investigator will, if still on-site, personally notify hospital officials. A letter to the same effect will then promptly be sent by OCR. This letter will notify the recipient hospital of the decision made concerning immediate referral to the Justice Department. It will not provide a formal finding concerning the investigation, which cannot be made until all information is analyzed and reviewed. (It may be, for example, that, although there is no

emergency requiring immediate legal action by the Justice Department, there is, or was, noncompliance.)

The Department believes this immediate notification procedure, stated in section (b)(7) of the appendix, will provide a basis for the hospital to assure the press and public that OCR's initial conclusion in connection with the investigation is that no infant is in imminent peril due to discriminatory withholding of medically beneficial treatment.

Confidentiality of Records

A number of commenters criticized the enforcement process on the grounds that it infringes on the confidentiality of the physician-parent relationship and the privacy of medical records. Some of these commenters referred to the confidentiality requirements of state law and professional ethical standards.

As stated by the Federation of American Hospitals:

> The physician may be required to inform the parents that anything they may say or decide must be disclosed to federal or state authorities if an investigation results. [P]arents will find that they have a choice between sharing vital information and counseling with their physician and having their thoughts and emotions revealed to a stranger or, alternatively, withholding information.

A suggestion for an additional confidentiality safeguard, submitted by the director of nursing of a Butte, Montana hospital, was to limit review of records to one investigator, on-site, with no copies made.

Response

HHS believes there is no sound legal basis to challenge the Department's right to access to medical records for the purpose of determining compliance with section 504, and that adequate safeguards exist to protect the confidentiality of records obtained by OCR in the course of civil rights investigations.

With respect to legal authority, a state law, such as one restricting access to certain records, cannot, under the Supremacy Clause of the United States Constitution, be used to prevent accomplishment of the full congressional purpose of a Federal law. Similarly, standards of particular profes-

sional groups may not frustrate or defeat a Federal statutory duty.

Section 504 establishes certain responsibilities of recipients and authorizes and directs Federal agencies to enforce the law. Existing regulations, 45 CFR 80.6(c) (made applicable to section 504 by 45 CFR 84.61), require:

> Each recipient shall permit access by the responsible Department official or his designee during normal business hours to such of its books, records, accounts, and other sources of information, and its facilities as may be pertinent to ascertain compliance with this Part.... Asserted considerations of privacy or confidentiality may not operate to bar the Department from evaluating or seeking to enforce compliance with this Part. Information of a confidential nature obtained in connection with compliance evaluation or enforcement shall not be disclosed except where necessary in formal enforcement proceedings or where otherwise required by law.

The requirement that recipients provide access to records necessary to determine compliance is essential to accomplishment of the congressional purpose in enacting section 504.

HHS has adequate safeguards to protect the confidentiality of medical records obtained during the course of a section 504 investigation. In addition to the regulatory provision (quoted above) protecting confidentiality, OCR does not release confidential information in connection with any Freedom of Information Act request. Nondisclosure is permitted under that Act for records, the release of which would constitute a clearly unwarranted invasion of personal privacy. As further protection, OCR permits deletion of the patient's and parents' names and other identifying information to the extent deletion will not impede OCR's ability to determine compliance.

The argument that the possibility that investigators will seek access to a medical file will cause parents to withhold vital information from the infant's physician is not persuasive. Courts and legislatures have repeatedly rejected arguments that exceptions to the principle of confidentiality of medical records and the physician-patient privilege would result in the withholding of information necessary to facilitate

proper treatment. There are many established exceptions in the law to the principle of doctor-patient confidentiality in connection with criminal and civil proceedings where the effective administration of justice requires access to information in medical records or provided to physicians. It is also noteworthy in this regard that the Federal Rules of Evidence do not include an express doctor-patient privilege.

With respect to the suggestions for additional safeguards submitted by a commenter, OCR has in some cases been able to limit review of records to one individual at the hospital, without the need to obtain copies. However, no assurances can be made that OCR can meet its responsibility to conduct a thorough investigation under these conditions. Also, in many cases it may be preferable for the hospital to send OCR the pertinent records (with identifying information deleted), perhaps avoiding the need for any on-site investigation.

IV. RELATED HHS ACTIVITIES

HHS has undertaken several other initiatives in cooperation with the medical community and disability organizations to improve the delivery of health care services to handicapped infants. Recently, a contact was awarded by the Office of Human Development Services, HHS to the John F. Kennedy Institute in Baltimore to develop a model for a working nationwide referral network for the developmentally disabled. Such a network, using today's sophisticated technology, will make it possible for the physician, parents, or care-takers of a developmentally disabled individual to query a single source for information about that disability and pinpoint the best or most appropriate places to get help any where in the country for that individual.

Under the terms of this award, the strong features of two important information systems are to be combined and regionalized. One is a data retrieval system for the particular use of practicing physicians. The other is accessible by the general public. The data base for the physician-oriented system was developed by the Kennedy Institute in Baltimore, using data supplied by the 38 HHS supported university-affiliated facilities around the country. The Amer-

ican Medical Association has a contract with the Kennedy Institute to include the Institute's data as an additional offering of the A.M.A.'s nationwide medical information network, or "MINET." It is available to every "MINET" subscriber who has a desk-top computer and a telephone.

This enterprise pulls together government, the private nonprofit sector, and organized medicine, in this case, the A.M.A., to make information available to physicians concerning access to specialized care for their patients and as well as to a broad variety of support services in the community.

The more consumer-oriented data system is now functioning in South Carolina to benefit the citizens of that state. The system carries information on access to care and community support services within the state. Any individual or family member can gain access to the system merely by dialing a toll-free "800" number.

The Kennedy Institute has an excellent concept of how such a network will function. Under the contract recently awarded, it is hoped the South Carolina Model will be expanded to seven other states in the region. The next step should then be to extend the system nationally and thus make available to all citizens the best information and the most appropriate resources relative to handicapping conditions.

The availability of such a resource should do much to take the insecurity out of one effort to rally support services for the handicapped newborn.

In addition to this nationwide referral network, HHS and the Department of Education, in cooperation with the coalition of medical and disability organizations who signed the "Principles of Treatment of Disabled Infants," are organizing an effort to develop teaching models for health care professionals on improving infant care, aiding the decision-making process and use of the nationwide referral network.

The Department believes that informational and educational efforts of this kind are also of great importance in advancing the principles underlying the final rules.

V. ADDITIONAL ANALYSIS OF COMMENTS

Section III above includes an explanation of the provisions of the final rules, including an analysis of pertinent comments submitted to the Department during the comment period on the proposed rules. This section is an analysis of other comments not directly related to specific provisions of the final rules.

A. LEGAL ISSUES

A significant number of commenters addressed legal issues relating to the application of section 504 to matters concerning health care for handicapped infants.

Statutory Construction of Section 504

A number of commenters argued that, as a matter of statutory construction, section 504 of the Rehabilitation Act of 1973 is inapplicable to matters concerning health care for handicapped infants. The arguments advanced by these commenters were:

(a) The statute does not specifically mention handicapped infants, and the statutory definition of "handicapped individual" should be construed as inapplicable to infants because its reference to substantial limitations on major life activities has no application to infants since all infants are dependent on the efforts of others for performance of all external life activities.

(b) The legislative history makes no mention of handicapped infants and indicates that the primary focus of Congress in enacting the Rehabilitation Act was matters relating to vocational rehabilitation, rather than medical matters; and although the statutory definition of handicapped individual was amended in 1974 to broaden its scope beyond vocational rehabilitation, including access to services such as medical care, there was no indication that the statute, as amended, was intended to cover medical judgments about the type of treatment given any handicapped individual. As stated by one commenter:

> There is not even a hint in the legislative history of the Act or its amendments that would indicate Congressional intent to apply section 504 to medical treatment

of severely handicapped infants. Rather, it is clear that Congress intended the Act to foster fruitful and independent living for handicapped individuals.

(c) The rulemaking history of the Department's section 504 regulations reveals previous HHS interpretations that section 504 is inapplicable.

Response

The Department's position remains unchanged. Section 504 clearly applies to matters concerning the provision of health care to handicapped infants, and nothing in the legislative history of the statute or rulemaking history of the Department's regulations suggests a credible interpretation to the contrary.

Section 504 provides:

> No otherwise qualified handicapped individual... shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance....

The statute defines a "handicapped individual" as

> any person who (i) has a physical or mental impairment which substantially limits one or more of such person's major life activities,... or (iii) is regarded as having such an impairment.

An infant is a person. If an infant has a physical or mental impairment which substantially limits major life activities, or is regarded as having such an impairment, the infant is a "handicapped individual" within the meaning of the law. If a hospital engages in a program or activity which provides medical services to infants and if that program or activity receives Federal financial assistance, it is a "program or activity receiving Federal financial assistance" within the meaning of the law.

If an infant who is a "handicapped individual" is "otherwise qualified" to receive the benefits of a medical services program or activity receiving Federal financial assistance, and is denied, solely by reason of his handicap, the benefits of those medical services, that infant is within the protection of section 504.

A key issue, therefore, in applying section 504 in any context is that the handicapped individual who was allegedly excluded from participation in, denied the benefit of, or subjected to discrimination under, a federally assisted program or activity be "otherwise qualified" to participate in, or benefit from, the program or activity. To be "otherwise qualified," the handicapped individual must, in spite of his or her present or anticipated physical or mental impairment, be able to meet the essential requirements for participation in the program or activity.

In the context of receiving medical care, the ability to benefit for a handicapped person is the ability to benefit medically from treatment or services. If the handicapped person is able to benefit medically from the treatment or service, in spite of the person's handicap, the individual is "otherwise qualified" to receive that treatment or service, and it may not be denied solely on the basis of the handicap.

Therefore, the analytical framework under the statute for applying section 504 in the context of health care for handicapped infants is that medically beneficial treatment and services not be withheld from a handicapped infant solely on the basis of the handicap.

The legislative history makes clear that by enacting section 504 Congress intended to eliminate all of the "many forms of potential discrimination" against handicapped people through "the establishment of a broad governmental policy." S. Rep. No. 1297, 93d Cong., 2d Sess. 38 (1974). The statute applies to all federally funded programs or activities, specifically including those that provide "health services." *Id.*

The rulemaking history related to the 1977 promulgation of the Department's section 504 regulations explained that the Department was not seeking to regulate with respect to the highly controversial issue of the rights of institutionalized persons to receive treatment for the condition which led to their institutionalization. Additionally, the regulation specifies that the provision of health care services generally to handicapped persons is a matter covered by the Act and the Department's rules. 45 CFR 84.52.

It is difficult to understand the theory of statutory construction that would distinguish the provision of health care services to qualified handicapped infants from the provision of other federally assisted benefits and services to qualified handicapped individuals.

The Department cannot subscribe to the theory that the definition of "handicapped individual" should be construed as inapplicable to infants because infants are dependent upon others for all major life activities. This argument appears to be based on a much too narrow view of what constitutes "major life activities." The Department's section 504 regulations define "major life activities" at 45 CFR 84.3 (j)(2)(ii), as: "functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working." Infants undertake at least some of these major life activities from the moment of birth.

Moreover, if this is the theory, the Department is unaware of the basis to be used in determining at what age the protections of section 504 would begin to apply.

In summary, the Department can find no clue in any bit of legal analysis or rational policy analysis to commend the notion that there is or should be a distinction in the application of section 504 based on the age of the handicapped individual.

It appears the real basis for the contention that section 504 is inapplicable in this context is that medical care is involved, rather than what some may perceive as much less complicated matters like distributing welfare benefits, developing transportation systems, administering housing programs, delivering social services, providing educational services, making employment decisions, and the like.

The Department agrees that matters relating to the provision of medical care are in some ways different from other aspects of applying section 504. For one thing, the consequences of discriminatory treatment may be much higher—a matter of life and death. Also, the analysis involved in determining whether discrimination exists may, in some cases, be much more subtle and difficult. But one aspect that appears the same in all applications of section 504 is that decisions regarding whether handicapped persons will receive the serv-

ices and benefits of programs and activities receiving Federal financial assistance are sometimes made, not on the basis of the individual's actual qualifications for, and ability to benefit from, those activities, but rather on stereotypes and prejudices concerning the limitations on major life activities faced by handicapped persons. Section 504 was enacted to eliminate these considerations from such decisions. And although the section 504 analysis may be more subtle (at least in some cases), it is an anomalous and bizarre theory that section 504 can properly be used to require that a ramp be built in a hospital to assure that handicapped persons not be denied access to medical services solely on the basis of their handicaps, but that statute may not properly be used to prevent the intentional act of allowing other handicapped persons to die in that hospital, solely because of their handicaps. The Department cannot subscribe to this theory.

In summary, the Department's position is unchanged. Section 504 clearly applies to the provision of health care for handicapped infants.

Separating the "Handicap" from the Condition Requiring Treatment

A number of commenters expressed views that the section 504 analysis summarized above is incapable of application in many or most cases because the handicapping condition and the condition requiring treatment are one and the same. This fact, the commenters argue, results in an inability to separate "medical judgments" from judgments relating to social, emotional, economic, or other nonmedical issues, concerning which unreasonable prejudices have often caused discrimination against handicapped individuals.

Response

Although perhaps subtle, the analysis required by the statutory framework is just as applicable in a case where the handicapping condition and the condition requiring treatment are the same as it is to the "simpler" case where two distinct conditions are involved.

In the "simple" case involving two distinct conditions, such as Down's syndrome and an intestinal obstruction, the Down's syndrome does not present a medical contraindica-

tion to surgical correction of the intestinal obstruction. There is no valid medical reason (assuming no other condications) for treating the Down's syndrome infant differently than an infant with the same intestinal obstruction and no Down's syndrome.

The same analysis applies where the handicapping condition and the condition to be treated are the same. In such a case the "handicap" is the physical or mental impairment the infant has or will have (or "is regarded as having") *after* completion of the treatment under consideration. In the case of an infant born with myelomeningocele, for example, the treatment which must be considered is surgery to close the protruding sac to prevent infection and other potentially fatal consequences. The "handicap" is the physical and/or mental impairment the infant is regarded as likely to have in future life. To the extent the myelomeningocele itself or other complications (such as respiratory problems, infection, anesthetic risk, or other factors) present, in the exercise of reasonable medical judgment, contraindications to the surgery, the infant is not able to benefit, in spite of his or her handicap, from the surgery. However, if the surgery would be medically beneficial, in that it would be likely, in the exercise of reasonable medical judgment, to bring about its intended result of avoiding infection or other fatal consequences, then failure to perform the surgery because of the anticipated impairments in future life offends section 504, as the withholding of surgery is *because* of the handicap and *in spite of* the infant's being qualified to receive the surgery.

In both the Down's syndrome and myelomeningocele examples, this analytical framework accomplishes precisely what Congress intended in enacting section 504: to overcome stereotypes and prejudices against handicapped persons who are, in spite of their handicaps, able to participate in, and benefit from, activities and services supported by Federal funds.

All of this is not to say that application of this analytical framework in every case will be easy. Nonetheless, in spite of the difficulties which may arise in case-by-case applications, the analytical framework focusing on the provision of

medically beneficial treatment to handicapped infants is the correct one under the statute, and is capable of application.

Applicability of Section 504 When Hospital Is Incapable of Providing Treatment

A number of commenters questioned the applicability of section 504 in cases where the hospital, due to lack of sophisticated equipment, medical specialists, or other factors, is incapable of providing the treatment needed by a particular infant. These commenters appeared to suggest that the Department would find such a hospital to be in violation of section 504 because it did not provide the medically beneficial treatment it was u able to provide.

Response

The answer on the applicability of the law in such a case is as clear as the applicability of common sense. Common sense indicates that if a patient needs treatment which a hospital cannot provide, the hospital will try to refer the patient to a facility that can provide it. If the patient is handicapped, the common sense response is the same. The failure of the hospital to itself provide the treatment is not "on the basis of the handicap"; rather, nontreatment is based on the fact that the hospital is incapable of providing the treatment.

Similarly, if the medically indicated course of action for any individual with a condition the facility is incapable of treating is to arrange for that individual to be transferred to a facility where the treatment can be provided, then this transfer cannot be denied to a qualified handicapped person (one who will benefit medically from it) on the basis of the person's handicap.

Responsibilities of Hospitals as Opposed to Physicians

Another challenge to the Department's application of section 504 to health care for handicapped infants was submitted by the Federation of American Hospitals:

> . . .A hospital cannot practice medicine. In fact, many state laws prohibit and punish the unauthorized practice of medicine. Nevertheless, the proposed rules place the responsibility for the physician's decision on the

> hospital. Moreover, assuming that discrimination on the basis of handicap exists, it is *not* discrimination on the part of the hospital, it is the discrimination of the physician and/or parents who are not recipients of federal financial assistance as that term is defined under the Rehabilitation Act. Therefore, insofar as they apply to hospitals, not physicians and parents, the proposed rules are also totally misdirected.

Response

The Department disagrees with the comment's implications that the law in any way requires hospitals to engage in the unauthorized practice of medicine, and that hospitals have no authority to prohibit discrimination by physicians.

It is the Department's view that a hospital has the authority to condition a physician's staff membership or renewal of membership on an agreement to abide by the hospital's policy of nondiscrimination. Indeed, the Department's conditions for hospital participation in the Medicare program require that a hospital have "an effective governing body legally responsible for the conduct of the hospital as an institution." 42 CFR 405.1021. Those conditions also require that a hospital have:

> a medical staff organized under bylaws approved by the governing body, and responsible to the governing body of the hospital for the quality of all medical care provided patients in the hospital and for the ethical and professional practices of its members.

42 CFR 405.1023.

Under those conditions the medical staff is also "responsible for support of . . . hospital policies." 42 CFR 405.1023(a). Standards set forth in the accreditation manual for hospitals, published by the Joint Commission on Accreditation of Hospitals, also recognize the responsibility of the governing body to adopt and approve bylaws consistent with all applicable laws and regulations. The accreditation manual also emphasizes that the governing body has the responsibility for the conduct of the hospital's operation and that the medical staff is responsible to the governing body.

It is the Department's position therefore that a hospital has the right to establish and implement a policy of nondiscrimination among its employees and medical staff, and that this does not constitute an unauthorized practice of medicine by the institution.

Applicability of Section 504 to Adults

Several commenters raised the issue whether section 504 would also be applicable to issues relating to medical care provided to adults. For example, the Department received the following comment from a doctor in San Antonio, Texas:

> As a doctor who practices on adult patients, what I find most worrisome about this whole sorry affair is that the reasoning behind the proposed rules applies at least as well to adults as to infants with congenital defects. Should every patient, no matter how old or ill, be forced to receive the "benefits" of cardiopulmonary resuscitation? Should a ninety-year-old man with a stroke which has caused him to develop pneumonia be subjected to weeks on a respirator in hopes of getting him well enough to go to a nursing home, where the same basic problem is sure to lead to another bout of pneumonia? Should a senile, combative eighty-year-old lady with a breast mass have a biopsy and mastectomy? Certainly a stroke and senility are handicaps if Down's syndrome is.

Response

Although section 504 is, of course, applicable to issues relating to health care provided to adults, the unique issues relating to health care for handicapped infants significantly affect the application of the law and justify the special procedures established by the final rules.

The special needs of infants and minors have long been recognized by most states, as its evidenced by the enactment of child abuse and neglect statutes. These statutes, in most instances, specifically reference the failure to provide necessary medical care to minors as constituting child abuse or neglect, and establish special remedial authorities.

In contrast, most adult patients are viewed by courts as being competent to give or withhold consent regarding medi-

cal treatment for themselves. In the case of adults incapable of making decisions, due to senility, mental retardation, or the like, courts have applied the "substituted judgment" doctrine to try to ascertain the incompetent patient's own wishes through available evidence and by asking what a reasonable person in the patient's situation would do.

The circumstances which give rise to the special procedures established by every state to protect children are the same circumstances which give rise to the special procedures established by the final rules to apply section 504 to matters relating to health care for handicapped infants.

Limitations on Obligations Imposed By Section 504

A number of commenters called attention to judicial decisions indicating limitations on the extent to which section 504 mandates that recipients of Federal financial assistance undertake substantial changes in their programs or activities.

As stated by the American Academy of Pediatrics:

> Case law interpreting section 504 suggests the existence of limitations beyond which the statute cannot reach, giving rise to the question of whether HHS' rule would impose on providers unwarranted affirmative action burdens. In *Southeastern Community College v. Davis*, 442 U.S. 397 (1979), the Supreme Court considered the claims of a licensed practical nurse that her denial of admission to a college nursing program on the basis of her hearing disability violated section 504. The college had determined that Davis' impairment was such that, even with a hearing aid, she would be unable to participate fully in the program and function effectively as a nurse. According to the plaintiff, however, the college should not have taken her handicap into account in determining whether she was "otherwise qualified" for the program, but, rather, should have confined its inquiry to her academic and technical qualifications. The Court rejected this argument, finding that section 504 "by its terms does not compel educational institutions to disregard the disabilities of handicapped individuals...." 442 U.S. at 405.
>
> Davis argued further that HHS regulations implementing section 504 required that the nursing program

be modified to accommodate her, to which the Court replied:

> If these regulations were to require substantial adjustment in existing programs beyond those necessary to eliminate discrimination against otherwise qualified individuals, they would do more than clarify the meaning of § 504. Instead, they would constitute an unauthorized extension of the obligations imposed by that statute. *Id.* at 410....

Response

The only affirmative step required of recipient hospitals by the final rules is to post an informational notice. As explained in the preamble, the Department has sought to tailor the notice, with respect to both its wording and the locations for its posting, so as to avoid any disruptive or administratively burdensome effects. The posting of notices to advise individuals of protections provided by Federal laws is very common in connection with a wide range of civil rights, health and safety, consumer protection, labor standards, and other Federal laws. The posting of this notice cannot be credibly argued to constitute the kind of excessive regulation prohibited by the *Davis* doctrine.

The other provisions of the final rule which affect hospitals, the clarification regarding access to records and the narrow exception to the ten-day notice rule, similarly impose no appreciable administrative burdens on hospitals. The provision of the final rules relating to state child protective services agencies also, as explained in the preamble, imposes no significant burdens.

The case-by-case application of section 504 and existing regulations, entirely separate from any mandatory provision of the final rules, is, of course, subject to the *Davis* limitations. However, as clearly evidenced by the guidelines set forth in the appendix to the final rules, these limitations have been fully complied with in connection with the Department's interpretations of the application of section 504 and in its enforcement processes.

Section 504, as the *Davis* decision recognized, requires the operation of a recipient's program in a nondiscriminatory fashion. The Department's interpretations and procedures

applicable in this context require no more. The guidelines in the appendix make clear the Department interprets section 504 as not requiring the provision of futile treatments and as respecting reasonable medical judgments. Further, they make clear that investigative procedures have been specially crafted to avoid substantial administrative burdens. The basis of the Supreme Court's decision in *Davis* was that because the Court found it unlikely that the plaintiff could benefit ultimately from the nursing program, the college's refusal to make substantial modifications to its educational program to accommodate the plaintiff was not discriminatory. The appendix guidelines make clear that the Department's interpretation of section 504 in this context carefully adheres to this ability to benefit requirement.

The *Davis* decision did not authorize the evasion of section 504 obligations under the guise that adhering to the nondiscrimination mandate may require some attention. However the courts ultimately refine the doctrine that there are limitations on the scope of section 504, it is the Department's firm position that those limitations are in no way touched by the mandatory requirements of the final rules, nor will they be touched by case-by-case application of the law consistent with the guidelines set forth in the appendix to the final rules.

Medicare and Medicaid as "Federal Financial Assistance"

A number of commenters also disputed the Department's legal authority for the rules on the grounds that participation by hospitals in the Medicare and Medicaid programs did not bring them within the coverage of section 504 on the grounds that Medicare and Medicaid are not "Federal financial assistance" within the meaning of the Act.

Response

The Department's position, consistently held since the Medicare and Medicaid programs were originally enacted in 1965, that Medicare Part A payments to hospitals and Medicaid constitute Federal financial assistance for purposes of applicability of title VI of the Civil Rights Act of 1964 and the nondiscrimination statutes modeled after it, including section 504, is unchanged.

Because the rules do not specifically refer to the Medicare or Medicaid programs, the validity of the rule is not dependent upon the Department's long-standing interpretation. However, hospital officials who believe their hospitals are not subject to these civil rights laws may wish to inform themselves of the Department's position and the substantial legal support for it.

The Department's position has been clear, unequivocal, and consistent. The appendix to the Department's title VI regulations lists Medicare and Medicaid as programs of Federal financial assistance. 45 CFR Part 80, Appendix A, Part 1, No. 121, and Part 2, No. 30. The appendix to HHS's section 504 regulations makes clear HHS's interpretation that the scope of jurisdiction of section 504 is the same as that for title VI. 45 CFR Part 84, Appendix A, Subpart A, No. 2.

The legislative history of the Medicare statute makes clear that Medicare payments to hospitals were intended to constitute Federal financial assistance for purposes of the applicability of title VI of the Civil Rights Act, and thus section 504 as well. Speaking on the floor of the Senate in support of the Medicare bill, Senators Ribicoff and Hart stated unequivocally that title VI was applicable to hospitals participating in Medicare. Senator Ribicoff: "[H]ospitals and other institutions have . . . to abide by Title VI of the Civil Rights Act." 111 Cong. Rec. 15803 (1965). Senator Hart:

> In addition to the new economic independence it will create, I am hopeful that the bill will promote first class citizenship in another fashion also. We decided last year, and wrote into law, that federal tax dollars collected from all the people may not be used to provide benefits to institutions or agencies which discriminate on the grounds of race, color, or national origin. This principle will, of course, apply to hospital and extended care and home health services provided under the social security systems, and *will require institutions and agencies furnishing these services to abide by Title VI of the Civil Rights Act of 1964*. Id. at 15813 [emphasis supplied].

In addition, the legislative history of the Civil Rights Act supports this position. In the most complete analysis of title VI contained in the House Judiciary Committee's Report,

the additional views of seven supporters of the legislation, uncontroverted in any section of the report, specifically made reference to the predecessor program to Medicaid and clearly stated congressional policy underlying title VI:

> In a related fashion, racial discrimination has been found to exist in vendor payment programs for medical care of public assistance recipients. Hospitals, nursing homes, and clinics in all parts of the country participate in these programs and, in some, Negro recipients have received less than equal advantage.
>
> * * * * *
>
> In every essential of life, American citizens are affected by programs of Federal financial assistance. Through these programs, medical care, food, employment, education, and welfare are supplied to those in need. For the government, then, to permit the extension of such assistance to be carried on in a racially discriminatory manner is to violate the precepts of democracy and undermine the foundations of government.

H.R. Rep. No. 914, 88th Cong. 2d Sess. (Additional Views on H.R. 7152 of Hon. William M. McCulloch, et al.).

Courts which have dealt with this issue have found Medicare and Medicaid to constitute Federal financial assistance for purposes of establishing civil rights jurisdiction. A recent such case is *United States* v. *Baylor University Medical Center*, 564 F. Supp. 1495 (N.D. Tex. 1983). Citing HHS regulations indicating that Medicare and Medicaid are Federal financial assistance, case law in which courts "have had little difficulty" in finding that they are Federal financial assistance, the legislative history of the Medicare statute, long-standing agency interpretation, and the broad construction which must be given to remedial civil rights statutes, the court found that Medicare and Medicaid are Federal financial assistance for purposes of section 504 coverage. The court also specifically rejected the medical center's argument that Medicare and Medicaid payments are exempt from the definition of "Federal financial assistance" on the grounds of being under contracts of insurance. The Court distinguished insurance programs, by noting that Medicare is funded by mandatory taxes and Medicaid by general revenues, rather than through a system of risk-based premiums.

Other cases supporting the position that Medicare and Medicaid payments are Federal financial assistance are *NAACP* v. *Wilmington Medical Center*, 657 F.2d 1332 (3d Cir. 1981) (the court noted its jurisdiction was based on the hospital's receipt of Medicare and Medicaid funding); *United States* v. *Cabrini Medical Center*, 497 F. Supp. 95, 96, n.1 (S.D.N.Y. 1980); *Cook* v. *Oschner*. No. 70-1969 (E.D. La., Feb. 12, 1979) (the defendants' argument that Medicare and Medicaid payments did not constitute Federal financial assistance was rejected by the district court during pretrial motions); *Flora* v. *Moore*, 461 F. Supp. 1104, 1115 (N.D. Miss. 1978); and *Bob Jones University* v. *Johnson*, 396 F. Supp. 597 (D.S.C. 1974), *aff'd.*, 529 F.2d 514 (4th Cir. 1975) (court held that VA benefits to students constituted Federal financial assistance to the university and noted their similarity to Medicaid).

The basic congressional policy underlying title VI, section 504 and related statutes is that federally funded programs and services are to be administered in a nondiscriminatory fashion. The Medicare and Medicaid programs were established for the purpose of providing medical service to people who otherwise might not be financially able to obtain them. The argument that somehow these federally assisted medical services were not intended to be within the reach of the nondiscrimination rule is clearly contrary to the basic congressional policy. Underscoring this is the fact that HHS spends billions of dollars annually for health care services to the aged, disabled and poor, and virtually all hospitals participate in these programs. According to data of the Health Care Financing Administration (HCFA), HHS, of approximately 6,930 hospitals, 6,737 participate in medicare and virtually the same number in Medicaid. In fiscal year 1982, total hospital costs in the United States were $136 billion. Of this, $47.9 billion were HCFA expenditures ($36.3 billion, Medicare, $11.6 billion, Medicaid). Approximately 36 percent of all hospital costs in the United States are financed through the Medicare and Medicaid programs. *See HCFA Statistics* (Publication No. 03155, Sept. 1983).

It should also be noted that there are no persuasive arguments for distinguishing Medicaid and Medicare on the ques-

tion of whether they constitute Federal financial assistance to hospitals. Although Federal Medicaid funds flow through the states, the states' relationship to the hospitals in Medicaid is essentially the same as that of the Federal government to the hospitals in Medicare. HHS regulations for both title VI and section 504 specify that recipients of Federal financial assistance include all subrecipients which receive funds from a recipient. 45 CFR 80.13(i), 84.3(f).

In addition, Medicare and Medicaid cannot be considered procurement contracts for purposes of the statutory exemption from civil rights jurisdiction in connection with such contracts. Unlike the relationship that exists under procurement contracts, health care providers promise only that if they serve an eligible beneficiary of the program, they will look to the government for payment of all but specified items. In addition, under Medicare and Medicaid the level of services is determined by providers who are not acting as agents for the government and are not discharging an obligation the government has assumed. Rather they are—with Federal assistance—engaging in activities they have long performed. In this respect Medicare and Medicaid payments are indistinguishable from grants to pay the costs of medical services. Indeed, those payments often cover medical costs of indigent patients that hospitals would otherwise be required to absorb pursuant to their other legal obligations. In contrast, under a procurement contract the government acts on its own account as a consumer of goods, such as typewriters and paper clips, or services, such as hotel accommodations and rental car services for traveling employees. The level of services under procurement contracts is determined by the government and not, as under Medicaid or Medicare, by the provider.

Furthermore, the Medicare and Medicaid programs do not fall within the statutory exemption from the definition of Federal financial assistance for any payments pursuant to "a contract of insurance or guaranty." 42 U.S.C. 2000d-1, 2000d.4 (title VI); 45 CFR 84.3(h) (section 504). The principal object of the Medicare and Medicaid programs is to provide service. Medicare and Medicaid programs cannot properly be characterized as, or analogized to, a contract of

insurance. Benefits under these programs are not measured by any fixed premium paid by the beneficiary to the government; the government reimburses for the reasonable cost incurred by the provider in rendering services. Missing from both reimbursement plans is that essential element of insurance—the assumption of risk. The Medicare and Medicaid programs do not purport to indemnify for nonpayment by the beneficiary. The hospital, in becoming a provider of services under these programs, agrees to look to the government for payment and to accept the reimbursement from the government as full payment, except for the deductible and coinsurance. The beneficiary does not incur any obligation to pay for those services which are covered by the agreement between the provider and the government.

Nor do Medicare and Medicaid constitute contracts of guaranty. Essential to a definition of a contract of guaranty is a primary obligation on the part of the individual for whom the guaranty is given. A contract of guaranty is a promise to pay or an assumption of performance of some duty upon the failure of another who is primarily obligated in the first instance. In contrast, the reimbursement provisions of the Medicare and Medicaid programs are not activated by the failure of the individual recipient to pay for the medical services covered by agreement between the government and the hospital.

It is the absence of these elements which distinguishes Medicare and Medicaid from programs that Congress intended to be excluded under the contract of insurance or guaranty exception, such as mortgage guarantees under FHA or VA and depositors' insurance under FDIC, where the role of the government is clearly as an insurer or guarantor and Federal monies are involved only if the private party does not meet his or her obligation. It is also noteworthy that the American Hospital Association apparently concluded in 1966, when Medicare was instituted, that hospitals receiving Medicare were recipients of Federal financial assistance for title VI purposes. The AHA solicited and printed in its journal a question and answer article prepared by the former Department of Health, Education and Welfare to help hospitals understand what they were required to do

to comply with title VI to receive Medicare funds. *See* "Hospitals and Title VI of the Civil Rights Act of 1964, Questions and Answers," *Hospitals*, June 1, 1966. Also, pursuant to 45 CFR 84.5, hospitals which participate in the Medicare and Medicaid programs have submitted assurances to HHS that they would comply with section 504 and the applicable regulations.

Accordingly, as demonstrated by this brief summary of points in support of the Department's long-standing position, hospitals which participate in the Medicare and Medicaid programs are recipients of Federal financial assistance for the purpose of establishing section 504 jurisdiction.

"Program or Activity" Receiving Federal Financial Assistance

Another argument presented by some commenters to dispute the legal authority for the proposed rule is that even if Medicare and Medicaid are "Federal financial assistance," they are not "a program or activity" which provides medical care to handicapped infants. The argument appears to be that, purportedly following the analysis of the government's brief to the Supreme Court in the pending case of *Grove City College* v. *Bell*, 687 F.2d 684 (3d Cir. 1982), *cert. granted*, 51 USLW 3611, February 22, 1983 (#82-792), the "program or activity" which receives Federal financial assistance in the form of Medicare and Medicaid payments to a hospital is the fiscal accounting office of the hospital.

As stated by the American Academy of Pediatrics:

> ...to the extent, then, that the government believes that Title IX cannot extend beyond the financial aid office, is difficult to understand how section 504 could extend to nurseries, maternity wards, and neonatal intensive care units simply because the medical expenses of primarily elderly Medicare beneficiaries are reimbursed in the accounting office.

Response

The Department believes this argument is without merit. The position advanced by the government in *Grove City* is that in determining what constitutes the Federally assisted program, it is necessary to examine both the nature of the

Federal program and the organizational practices of the recipient institutions. *Grove City* involves the Basic Education Opportunity Grants program (BEOG), in which grants are made to students and used by the students to pay for tuition, fees, room and board. The recipient institutions operate financial aid programs under the direction of a financial aid office, with a separate budget and a specific purpose, to provide financial aid to students who otherwise could not afford to attend the college. BEOG's are one component of the college's financial aid program. In view of the nature of the Federal BEOG program and the organizational practices of colleges, it is the college's financial aid program that receives the Federal assistance. Although, conceivably, an effort could be undertaken to "trace" the "ripple effects" of the BEOG money throughout the college, the government's position in *Grove City* is that this is not what Congress intended in enacting the program specificity requirement in the applicable civil right statutes.

The circumstances involved in connection with Medicare and Medicaid reimbursements to hospitals are entirely different from those involved in BEOG's and colleges. Rather than providing assistance to a general financial aid program operated by the recipient, Medicare and Medicaid payments to hospitals are primarily for particular medical services provided to particular patients who received services in particular units of the hospital. It is services provided to particular beneficiaries by the hospital's operating room, x-ray department, laboratory, pediatrics ward, or other organizational units that give rise to the Federal reimbursements. In addition, the hospital's organizational and accounting practices provide for Federal reimbursement for a proportionate share of administrative costs, housekeeping, depreciation of physical plant, and other general expenses, all specifically itemized and specifically eligible for reimbursement.

Also unlike colleges, "tracing" Medicare and Medicaid reimbursements within hospitals is not dependent upon looking for "ripple effects" of the Federal funds. Rather, it is the specific identification of actual services and costs which gives rise to reimbursements based specifically thereon.

Therefore, the Federally assisted program of a hospital is not, as a commenter suggested, the accounting office of the hospital, any more than the Federally assisted program of a college is the accounting office or comptroller. An examination of the applicable Federal programs and the recipient's organizational practices makes clear that the issues presented in the *Grove City* case, and the positions taken by the government in that case, do not undermine the legal basis for the final rules or the application of section 504 to health care for handicapped infants.

It should also be noted that whatever subtleties or twists are ultimately associated with the interpretation of "program or activity," the final rules specifically accommodate the program specificity requirement pertaining to the posting of the informational notice as applicable to each recipient that provides health care services to infants "in programs or activities receiving Federal financial assistance." If, on the basis of the Supreme Court's eventual decision in *Grove City* or other factors, limitations evolve on what programs or activities of hospitals are covered by section 504, those limitations will be accommodated by the text of the rules.

Services vs. Employment as Jurisdictional Limitation

The Federation of American Hospitals advanced another argument in behalf of the proposition that the Department has no legal authority to issue the final rules. The Federation commented:

> The Rehabilitation Act of 1973 (Pub. L. 93-112) does *not* apply to hospitals. Federal circuit courts of appeal which squarely address the issue uniformly hold that the Act does *not* apply to hospitals as recipients of Medicaid or Medicare funds. These courts have held that the Rehabilitation Act applies to recipients of federal financial assistance if, and only if, that assistance has the primary objective of providing employment.
>
> In *United States* v. *Cabrini*, 639 F.2d 908 (2d Cir. 1981), the Court . . . [held] that the Office for Civil Rights was not authorized to investigate a complaint by a hospital employee that he was discharged for mental disability.... *Tragesar* v. *Libbie Rehabilitation Center*,

Inc., 590 F.2d 87, 89 (4th Cir. 1978), *cert. den'd*, 442 U.S. 947; *Scanlon* v. *Atascadero State Hospital*, 677 F.2d 1271, 1272 (9th Cir. 1981); see, also, *Carmi* v. *Metropolitan St. Louis Sewer District*, 620 F.2d 672, 674-675 (8th Cir. 1980), *cert. den'd*, 101 S. Ct. 249 (1980)...

As there is no legal authority supporting the proposition that the Rehabilitation Act of 1973 applies to hospitals receiving Medicare and Medicaid funds since the primary objective of those programs is *not* employment; the proposed rules must be withdrawn.

Response

The Federation's legal argument is incorrect. The *Tragesar/Carmi/Cabrini/Scanlon* line of cases holds that section 504 does not provide jurisdiction *over employment practices of recipients* unless the Federal financial assistance has the primary objective of providing employment. These cases held that section 505(a)(2) of the Rehabilitation Act, making the "remedies, procedures, and rights set forth in title VI of the Civil rights Act of 1964" applicable to section 504, incorporated the restriction in section 604 of the Civil Rights Act of 1964, which makes title VI inapplicable to employment practices unless the Federal financial assistance has the primary objective of providing employment. Two circuit courts have recently held that the reference to title VI procedures in section 505 did not intend to incorporate the employment restriction. *Jones* v. *Metropolitan Atlanta Rapid Transit Authority*, 681 F.2d 1376 (11th Cir. 1982), *petition for cert. pending*, No. 82-1159 (filed January 11, 1983); *LeStrange* v. *Consolidated Rail Corporation*, 687 F.2d 767 (3d Cir. 1982), *cert. granted*. The Supreme Court is expected to decide this issue during its present term.

Regardless of the merits of that issue, it has no relevance to the final rules. No case has held, as none could based on the clear statutory language and congressional intent of section 504, that section 504 applies only to a very narrow segment of employment practices, and has no applicability to the provision of services and benefits under programs and activities receiving Federal financial assistance.

B. ENFORCEMENT PROCESSES

A prior section of this preamble discusses investigative procedures of the Department applicable in the context of health care for handicapped infants and an analysis of related comments. This section discusses other comments pertinent to this issue.

Sanction for Non-Compliance

A number of commenters stated objections to the sanction for non-compliance, termination of Federal financial assistance. The basic thrust of these comments was that termination of all or a portion of a hospital's Federal financial assistance would be unfair in the context of difficult treatment decisions, later judged by HHS to be in non-compliance with section 504. As stated by the American Hospital Association:

> The penalty for even inadvertent violation would be severe. The Department asserts authority and threatens to terminate all federal financial assistance that the individual or institution may be receiving. Moreover, the threat of such penalties may encourage physicians and others to refuse to participate in programs funded by the Federal government, particularly those supporting specialized treatment facilities for the newborn. In cases where the institution depends for operation on significant federal funds unrelated to handicaps, this policy may, for example, cause the closing of neonatal units to avoid the risk of losing federal funds. Such a result could reduce access to needed care for many infants who could be helped with safe, timely and effective treatment.

Response

It is correct that under the law, noncompliance with section 504 can result in termination of Federal financial assistance to the particular program or activity, or part thereof, in which the noncompliance has been found. However, the existing procedural and legal requirements applicable to any action to terminate Federal financial assistance are more than adequate to protect against an unfair result.

The Rehabilitation Act provides, in section 505(a)(2), that the remedies, procedures and rights set forth in title VI of

the Civil Rights Act of 1964 shall be applicable to actions to enforce section 504. These title VI procedures provide substantial due process protections.

First, before Federal financial assistance can be terminated, the recipient must have an opportunity for a hearing before a court or administrative law judge, who must expressly find that there has been a failure to comply with the law or applicable regulations.

Second, before Federal financial assistance can be terminated, there must be a finding that compliance cannot be secured by voluntary means. Therefore, a recipient that has been found to have violated section 504 in connection with the health care provided to a handicapped infant will not lose its Federal funding unless it refuses to adopt the standards or procedures necessary to prevent future noncompliance.

Third, in any case, the burden of proof that there has been noncompliance and that it cannot be corrected by voluntary means is on the government. The standards for this determination are those set forth in the appendix to the final rules which includes the guideline regarding deference to reasonable medical judgments.

Fourth, the Department's regulations provide for appeal of adverse administrative law judge decisions to the Department's Civil Rights Reviewing Authority, which is independent from the Office for Civil Rights. Recipients may then seek review by the Secretary of the decisions of the Reviewing Authority. Further, the Department's final decision is subject to judicial review.

Therefore, there is no basis for an assertion that Federal financial assistance can be precipitously terminated on the basis of some subjective determinations by a handful of bureaucrats. In fact, due primarily to the statutory requirement that recipients be given full opportunity to voluntarily comply, the chance, based on all prior governmental experience under title VI and the statutes modeled after it, that any recipient will actually lose its Federal financial assistance is rather remote.

OCR Investigations at Strong Memorial Hospital and Vanderbilt University Hospital

In support of criticisms of OCR investigations, a number of commenters cited reports of hospitals which were subjects

of OCR investigations at the time the interim final rule was put into effect in March. As stated by the American Hospital Association:

> The mischief of the federal hotline enforcement mechanism was illustrated graphically during the short life of the March rule by the occurrences at Vanderbilt University Hospital in Nashville and Strong Memorial Hospital in Rochester, NY. In the Vanderbilt case, an anonymous hotline caller alleged that ten named children at the hospital were not being fed or given proper medical care. A federal "Baby Doe squad" (consisting of lay officials from the regional and national staffs of the Office of Civil Rights and a hired neonatologist) arrived at the hospital that evening and met with the attending physicians for each of the children, the chief of pediatrics, the chief pediatric resident, and the associate director for nursing, after which the neonatologist examined each child. On the following day, the investigative team examined medical records and interviewed nursing staff, hospital administrators, and the chief of pediatrics.
>
> [The investigation] resulted in the delayed discharge of one patient, delayed the transporting of children to scheduled surgery, necessitated the re-ordering of laboratory reports, diverted nurses from patient assignments, delayed nursing shift reports, and consumed, in total, substantial amounts of professional time that otherwise would have been devoted to the care of patients, including the infants who were the subjects of the investigation.
>
> The Strong Memorial experience was strikingly similar and even more disturbing. An unidentified hotline caller, whose only information concerning the case apparently came from a newspaper report, triggered an investigation regarding the treatment of conjoined twins in that facility. An identically constituted investigative squad arrived at the hospital, though without any statement of investigative authority or written requests for hospital records. The hospital complied nonetheless with the investigators' requests, only to have the team disagree as to which of them was entitled to the information. The neonatologist member of the team subsequently departed upon learning that the in-

vestigators had failed to obtain the parents' consent to examine the infants.

The effects of the investigation in this case went well beyond the diversion of patient care resources and delays in treatment. The parents of the conjoined infants were subjected to substantial undesired publicity. Parents of other critically-ill children were led by this publicity and the lack of clarification from federal investigators to become apprehensive about the adequacy of care provided at Strong Memorial. Before the investigation concluded, one family removed its seriously-ill child from the facility prior to the completion of treatment, on the belief that the hospital was intentionally harming children.

Response

The Department strongly disputes the accounts of these investigations provided by personnel affiliated with the two hospitals. The reports referenced by commenters appear to be based upon affidavits prepared in connection with litigation initiated by the American Hospital Association challenging the implementation of the March interim final rule. Contrary to these reports, both of these investigations were conducted very expeditiously and professionally, and every effort was made to minimize any disruption to the hospitals. In addition, during the course of these investigations (and prior to their being raised in the litigation), officials of neither hospital complained to OCR regarding the conduct of the investigations, nor, in either case, did hospital personnel complain to OCR personnel that the investigations were causing significant disruptions to the patient care activities of the hospital.

With respect to the Strong Memorial Hospital case, the following are the pertinent facts of the investigation:

a. On the morning of March 29, 1983 (seven days after the effective date of the interim final rule), a complaint was received on the hotline about conjoined infants recently born at Strong Memorial Hospital in Rochester, New York.

b. An investigative team consisting of one investigator from the Washington Office and two from the New York Regional Office was sent to the site to investigate. The team

arrived at approximately 4:30 p.m. Arrangements were made to have a medical consultant also travel to the site.

c. The team met with a hospital administrative officer and the attending physician. The attending physician reviewed the infants' condition and status. He mentioned that there was a no-resuscitation order in effect for the twins, should cardiac arrest occur.

d. The attending physician told OCR that the parents were concerned about publicity. OCR assured him that OCR would not discuss the case with the media or otherwise publicize OCR's investigation.

e. The OCR team made no request to interview other staff at that time. The administrator produced a copy of the medical records. The Washington Office investigator received it and said it would not be necessary to produce another copy for the Regional Office. Throughout the investigation, the administrator and attending physician were cooperative and helpful. The attending physician asked the team leader to tell the OCR medical consultant that he could be called late and would be glad to come to the hospital and meet with him, show him the medical records, and let him view the infant. The administrator asked to be called when the medical consultant arrived. The OCR team left the hospital at about 7:30 p.m.

f. The OCR medical consultant arrived in Rochester about 9:15 p.m. and met with the investigative team. Apparently based on a misimpression of his role, the consultant stated he would not review the records or go to the hospital to meet with the physician or view the infants unless the parents consented.

g. On the morning of March 30, 1983, the OCR team and the OCR medical consultant had a telephone conversation with the administrator. He said that he wished the OCR team would not return to the hospital because that investigation was receiving publicity. The team leader decided there was no need to return to the hospital.

h. In summary, the investigative team was on site only three hours in the late afternoon and early evening of March 29.

With respect to Vanderbilt University Hospital, following are the pertinent facts of the case:

a. OCR received a hotline telephone call at 11:45 a.m. on March 23, 1983 (the day after the effective date of the interim final rule), alleging that ten infants at Vanderbilt University Hospital were not receiving treatment and/or nourishment.

b. From 9:30 p.m. to 11:45 p.m. on March 23, 1983, the OCR investigative team, consisting of two investigators from the Atlanta Regional Office, one from the Washington Office, and the OCR medical consultant, met with various members of the hospital staff to discuss the current status of the ten infants.

c. After this meeting, from midnight until 12:30 a.m., the OCR medical consultant physically viewed the infants on the regularly scheduled "rounds" in the company of the Chief Pediatric Resident and the Chief of Pediatrics.

d. From 8:00 a.m. until 2:45 p.m. on March 24, 1983, the OCR investigators and medical consultant reviewed the available medical records of the ten children. Medical records were given to OCR in groups of four and retrieved as needed by the Associate Director of Nursing and other members of the Vanderbilt staff. The Associate Director of Nursing and the hospital staff members were very cooperative, and at no time did they indicate to the investigative team that the review of records was causing any problem. In only one instance did they indicate they needed a chart, and OCR immediately relinquished it. That chart was not subsequently made available for review that day, but a copy of it was mailed to OCR.

e. All records were reviewed with the understanding that if they were needed for patient care they would be retrieved. Computer printouts detailing the admitting diagnosis, age, physician assigned to the case, service area, and the date of admission or transfer for all ten children were given to the OCR team. The Associate Director of Nursing stated that this printout was readily available because the information was kept on-line for billing purposes and this would not interfere with patient care. The bedside charts were copied

and given to OCR at the end of day because they were needed for patient care.

f. Following the OCR review of the medical records, from approximately 2:45 p.m. to 4:00 p.m. on March 24, 1983, the OCR team interviewed the available nurses who were involved in the primary care of the infants. Five nurses were interviewed for approximately 10 to 15 minutes each. The selection of the nurses was left to the discretion of the Associate Director of Nursing; she scheduled them so that patient care would not be disrupted.

g. At no time did the Chief of Pediatrics or Associate Director of Nursing indicate that the OCR investigation was placing patients in jeopardy.

h. The hospital staff asked the OCR team for a preliminary statement of findings. The team leader responded that OCR investigators are not authorized to make findings during an investigation. An investigative report would have to be prepared following the investigation, and this would have to be reviewed before the agency could issue findings.

i. The total time spent on-site to investigate the circumstances relating to all ten infants was approximately eleven hours. The total time occupied of the two Vanderbilt doctors directly involved was seven and one-half hours. Every effort was made to minimize any disruption, and at no time during the investigation did hospital personnel complain to OCR that the investigation was disrupting patient care.

Therefore, contrary to the reports of hospital officials, prepared to support litigation against the Department, these investigations were conducted professionally and every effort was made to minimize any disruptions.

Concerning the report that, according to a hospital official, one family withdrew a seriously ill patient from the Strong Memorial Hospital before completion of treatment due to fears that the hospital was intentionally harming children, caused by their reading of local newspaper accounts of the investigation, the report provided no further details, and the department has no basis to confirm the event or the motivations for it. However, the firm policy of not commenting to the media regarding an open investigation was adhered to strictly in the Strong Memorial Hospital case. Media atten-

tion was not provoked by OCR, nor did OCR make any statement to the media which could have implied any belief by OCR that the allegations of the complaint were substantiated.

Danger of Overtreatment

Several Commenters expressed the concern that the existence of OCR's enforcement process would cause hospitals and health care professionals to "overtreat"an infant. An example of this is a case in which the attending physician or physicians have concluded on the basis of reasonable medical judgment that treatment would be futile, but, due to a fear that an OCR investigation might come to a contrary conclusion, nevertheless provide futile treatment, which, while prolonging the process of dying, causes suffering to the infant and severe distress to the infant's parents. In connection with adverse ramifications of overtreatment, attention was called to the experiences of one family, as presented in a recent book, *The Long Dying of Baby Andrew* (Little, Brown and Co., Boston, 1983).

Response

The Department believes that whatever the dangers are that physician misjudgments will lead to "overtreatment" of infants, those dangers are not increased by the existence of section 504 or the determination of the Department to see that it is effectively enforced. As indicated above, section 504 does not require that futile treatments, which will do no more than prolong the act of dying, be provided. Moreover, OCR decisions concerning compliance or noncompliance with section 504, informed by the expert evaluation of qualified medical consultants, do not interfere with reasonable medical judgments. Also, in any case, reviewing whether certain care was medically indicated and denied on the basis of the infant's handicap, there are extensive due process protections to assure accuracy of fact finding. Furthermore, even where there is an ultimate finding, after exhaustion of all due process rights, of noncompliance of section 504, no sanction can be implemented unless the recipient hospital refuses to adopt procedures to bring it into compliance.

The Department agrees that in a "close case" it may be prudent to preserve the status quo pending additional consideration regarding whether certain possible treatments are medically indicated, whether that additional consideration is by specialists at the hospital, by medical professionals at a more specialized facility, by some internal hospital review board, or by some state or federal agency. In such a case, the usual practice in most hospitals likely would be to continue life-sustaining care until the appropriate analysis has been secured.

C. ALTERNATIVE APPROACHES

In addition to proposals discussed in the preamble concerning establishment of Infant Care Review Committees, the Department received other suggested alternative approaches.

AMA Proposal: Further Study Prior to Action

The American Medical Association proposed that, rather than adopting any regulation, the Department should initiate a study to include: compilation of data on the incidences of each type of severe impairment in newborns and of successful treatment, unsuccessful treatment and nontreatment in each category; identification of the issues involved in medical management and of mechanisms currently used by hospitals and states; determination of the availability of facilities, financial resources, and public and private social services; and an assessment of the impact of the various alternative means of responding to situations involving severely impaired newborns, including such factors as the ongoing treatment of newborns, the families of severely impaired newborns, the operation of health care facilities, the confidentiality of patient-physician relationship, the malpractice and disciplinary risks of health care providers, the availability of facilities and resources, and the costs of care.

Response

The AMA's proposal for an elaborate study prior to taking any action concerning this matter is not acceptable to the Department. The Department does not believe it is necessary—or in some respects, even possible—to generate

definitive data, information or conclusions on many of the issues identified in the AMA's study proposal.

Much of the data the AMA proposes be compiled concerning the incidence rates of every classification and degree of serious impairment, of respective modes of treatment, of rates of success, nonsuccess and nontreatment, and of issues, mechanisms, resources and costs is probably impossible to compile. These matters are the subject of an entire discipline of medical practice and study. To suggest that a government study will somehow generate conclusive information on these issues appears naive at best.

The call for a study of the resources available and the costs of care for newborns appears aimed at identifying an aggregate cost to society of putting into practice the principle of providing all handicapped infants with medically beneficial treatment. Because there are no reliable data available on the extent to which handicapped infants are now denied medically beneficial treatment, it would appear impossible to develop even reasonable guesses regarding aggregate costs. Of course, in the overall context of all health care expenditures in the United States, the costs are certain to be relatively small.

In question 6 included in the preamble to the July 5 proposed rule the Department sought input on this cost issue by asking for "examples of cases where medically indicated treatment would, but for the legal requirements of section 504, be withheld." No information was submitted to the Department in response to this question which provides a basis for meaningful cost projections. Although the AMA did not address the issue, other major medical organizations who commented on the cost issue indicated that cost should not be a determinative factor in deciding upon treatment for seriously impaired newborns.

The Department agrees there is utility in assessing the impact of various alternative means of addressing and responding to situations involving severely impaired newborns. Much of this preamble focuses on precisely this issue. Although the AMA did not identify the "various alternative means" it believes to exist to deal with this issue, based on the comments received by the Department, there would ap-

pear to be three major approaches: (1) Enforcement of section 504 (hereinafter "the section 504 approach"); (2) review by hospital review boards, such as Infant Care Review Committees (hereinafter "ICRC approach"); and (3) the traditional doctor-parent approach.

Concerning impact on treatment of newborns, the section 504 approach is most directly focused on the provision of medically beneficial treatment. The ICRC approach would be organized to have this as its objective, but lacks a mechanism to assure this as a relatively uniform result among thousands of hospitals. The connection between actual practice and this objective appears most potentially attenuated under the traditional doctor-parent approach, under which there are many thousands of individual decisionmaking units.

With respect to the impact on families to the extent some parents would not consent to medically beneficial treatment, the traditional doctor-parent approach would appear least likely, given the lack of a mechanism to facilitate uniformity, to resort to the system provided by State law to review the propriety of parental decisions. The ICRC approach appears more likely, and the section 504 approach most likely, to produce this result in that they incorporate standards that the lack of parental consent for medically beneficial treatment must be brought to the attention of the appropriate state agencies.

Concerning the impact on the operation of health care facilities, the traditional doctor-parent approach would appear to have the least impact because the facilities have no formalized involvement in the decisionmaking process. Both the section 504 approach and the ICRC approach would likely result in greater involvement of the health care facility.

With respect to the confidentiality of patient-physician relationships, the traditional physician-parent approach is most protective of confidentiality in that it does not provide for the sharing of information with others. Both the section 504 approach and ICRC approach involve the sharing of information with others, but both incorporate adequate confidentiality safeguards.

With respect to the impact on malpractice and disciplinary risks (assuming that by disciplinary risks, the AMA is referring to revocation of medical licenses, or the like) of health care providers, to the extent physicians have malpractice or disciplinary vulnerabilities relating to incorrect diagnoses or inadequate knowledge of prevailing medical judgments regarding indicated treatments, approaches would facilitate the avoidance of failure to provide medically indicated treatment would appear to reduce those vulnerabilities. Because none of the approaches involve doctors or hospitals overruling parental decisions, and because reports to State agencies of suspected instances of neglect of children are immunized by state law from legal vulnerability, none appear to increase malpractice or disciplinary risks in the context of actions which would be taken when parents refuse consent for medically beneficial treatment.

With respect to the impact on costs, available resources, and available facilities, to the extent the different approaches affect the likelihood that handicapped infants will receive medically indicated treatment, these factors will be correspondingly affected. However, the Department is unaware of any data base for quantifying these factors.

In summary, the Department believes adequate information is on the record to provide a basis for prudent and informed decisions on this issue. Regarding several of the issues raised by the AMA proposal, the Department agrees there would be advantages in having more detailed information and data. However, obtaining more definitive information on some of these issues is impracticable or impossible due to the lack of reliable data base and a viable methodology to obtain better data. Therefore, the Department believes there would be very little to be gained from another government study of this issue.

D. FACTUAL BASIS FOR FINAL RULES

NPRM Explanation

A number of commenters challenged the Department's factual basis for the proposed rule, as set forth in the July 5 notice of proposed rulemaking. The points argued in support

of the position that the factual basis did not provide a sufficient foundation for the regulation were:

(a) Judge Gesell questioned the factual basis for the March 7 rule.

(b) The 1973 article by Drs. Duff and Campbell of the Yale-New Haven Hospital documenting that of 299 consecutive deaths occurring in that special care nursery, 45 (14%) were related to withholding treatment, cited in the preamble to the proposed rule, was too old to be reliable.

(c) The several specific cases cited in the preamble had various probativity defects.

(d) The 1977 article reporting the results of a survey of pediatricians suggesting discriminatory attitudes was outdated, not statistically valid, and otherwise lacked current probative value.

(e) The findings of the report of the President's Commission for Study of Ethical Problems in Medicine and Biomedical and Behavioral Research entitled *Deciding to Forego Life-Sustaining Treatment* contradict the Department's factual basis.

(f) Because "discrimination against the handicapped in the delivery of health care services does not only involve handicapped newborns," there is "no compelling rationale for a set of rules targeted solely at this population."

Response

The Department continues to believe that a substantial factual basis exists for the proposed rule. First, it should be noted that Judge Gesell, although he found many relevant factors to have been inadequately considered in connection with issuance of the March 7 rule, did not find the factual basis inadequate to support "undertaking a regulatory approach to the problem of how newborns should be treated in government-financed hospitals."

Second, the arguments that the well-documented Duff and Campbell study is outdated are based on the personal opinions of several commenters. These personal opinions, although in some cases those of highly respected medical professionals, were not backed up by any empirical data even

remotely resembling the very detailed evidence of the Duff and Campbell study.

Third, the conclusion of the President's Commission that decision making about seriously ill newborns "usually adheres" to proper standards cannot be fairly represented as evidence that handicapped newborns should be exempt from basic protections of the law prohibiting discrimination on the basis of the handicap.

Fourth, regardless of the caveats concerning the age of particular cases or the lack of a conclusive finding of illegal discrimination, the several specific cases cited in the preamble to the proposed rule support the proposition that handicapped infants may be subjected to unlawful discrimination.

Fifth, in the absence of any empirical studies or data to bolster their personal opinions, the commenters who suggested that the results, published in 1977, of the survey of pediatricians' attitudes are outdated are not convincing. The article, "Ethical Issues in Pediatric Surgery: A National Survey of Pediatricians and Pediatric Surgeons," 60 *Pediatrics* 588, reported the results of a survey of 400 members of the Surgical Section of the American Academy of Pediatrics and an additional 308 chairpersons of teaching departments of pediatrics and chiefs of divisions of neonatology and genetics in departments of pediatrics. Responses were received from 267 of the former group (66.8%) and 190 of the latter (61.7%). Responses were anonymous. Among the results of the survey were:

—76.8% of the pediatric surgeons and 49.5% of the pediatricians said they would "acquiesce in parents' decision to refuse consent for surgery in a newborn with intestinal atresia if the infant also had Down's syndrome."

—23.6% of pediatric surgeons and 13.2% of pediatricians would *encourage* parents to refuse consent for treatment of a newborn with intestinal atresia and Down's syndrome. Only 3.4% of pediatric surgeons and 15.8% of pediatricians would get a court order directing surgery if the parents refused.

—63.3% of the pediatric surgeons and 42.6% of the pediatricians said in cases of infants with duodenal atresia and Down's syndrome, where they "accept

parental withholding of lifesaving surgery," they would also "stop all supportive treatment including intravenous fluids and nasal gastric suction."

—62% of all respondents who believe that children with Down's syndrome "are capable of being useful and bringing love and happiness into the home" would nevertheless acquiesce in parents' decisions not to allow surgery for the atresia. Only 7% who so believe indicate that they would go to court to require surgery.

Sixth, there is no requirement in law or policy for the government to prove the magnitude of illegality before establishing basic mechanisms to allow for effective enforcement of a clearly applicable statute.

Evidence of Problems Submitted by Commenters

Additional evidence of the risk that handicapped infants may be subjected to discrimination was submitted by commenters. For example, the Spina Bifida Association of America stated:

> Unfortunately, the SBAA has direct experience of cases in which this principle [of nondiscrimination] has not been followed—instances in which children with spina bifida have been initially denied appropriate treatment. Pediatric neurosurgeon Dr. David McClone of Chicago Children's Memorial Hospital, a member of SBAA's Professional Advisory Committee, has found that 5% of the children with spina bifida referred to him have been victims of treatment denial. Most of these cases, he believes, resulted from ignorance of current therapies and their impressive outcomes.

The Department received a number of comments from practicing nurses regarding the problem and need for the proposed rule. For example, from a Lexington, Kentucky, nurse:

> I am a registered nurse and have worked in the labor and delivery area, newborn nursery and intensive care nursery.... I think the average American would be shocked at the decisions that are made regarding "non-perfect" infants. I have personally heard physicians and nurses talk to new parents about their child and persuade the parents to "let the child die and therefore end

its suffering"—which really meant "let us starve your child to death"—that is certainly not a humane way to "let a child die."

A nurse in Boca Raton, Florida, wrote:

> I am an RN with a specialty in maternal-child health. In the past few years I have had to witness the deaths of innocent children in hospitals where a decision was made not to continue with medical care and assistance.

Another nurse wrote:

> As a nurse (RN) in a neonatal ICU, I feel compelled to write and voice my support of the "Baby Doe rule" now proposed.... Many doctors and nurses openly support withholding or withdrawing medical care.... Due to the ethics of the medical director of the unit, this has only been done once or twice to my knowledge. I would report any cases of neglect I knew of if this number and service were available.... An outside third party is needed to police the cases. Please allow some method of reporting and investigating these babies' cases to be available.

From a nurse in San Diego, California, came the following comment:

> [A]s a practicing registered nurse myself, I believe such regulations permit nurses and staff to act in a patient's best interest—life itself!—without fear of harassment and possible job loss.

In addition, some commenters who opposed the proposed rule appeared to acknowledge that there is a risk that handicapped infants will not receive medically beneficial treatment. For example, the American Society of Law and Medicine, a national, nonprofit professional association, stated:

> There can be no question that some decisions to end life-sustaining care for newborns have been made inappropriately, even if the frequency of this problem has not been established.

Another example of this is the comment by the chairman of the division of pediatrics of a hospital in Illinois:

> We are acutely aware that handicapped individuals (*not* most handicapped newborns) are systematically discriminated against in our society. We are also acutely aware that we, like virtually all members of our

> society, are guilty of having prejudicial beliefs and attitudes about the handicapped. That pediatricians and other health care providers have acted on these negative beliefs and attitudes should come as no surprise. That parents, at least in the initial phase of their relationship with a handicapped newborn, should wish to be spared what is perceived as a burden or even wish that the infant had never been born should come as no shock.
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> * * * * *
>
> We wholeheartedly agree that in the past these obviously critically important decisions have not been accorded the degree of reflection and care they are due. Given the wide range of possible technological interventions now possible; given the changing conception of the appropriate role of physician and parents in such decisions; and given the need for public accountability for such decisions—we support the idea that the manner in which such decisions have been made in the past needs critical reexamination.

Another example is the comment of the American Academy of Pediatrics:

> The traditional method of a single physician making such judgment [regarding treatment], without exposure to other persons having additional facts, experience, and points of view, may lead to decisions, which, in retrospect, cannot be justified.

Response

The Department believes these comments provide additional support for the Department's conclusions that available evidence indicates there are cases in which handicapped infants are at risk of having life-sustaining, nourishment or medically beneficial treatment withheld solely on the basis of their present or anticipated physical or mental impairments, and that this evidence constitutes a substantial foundation for the establishment of basic procedural mechanisms to facilitate enforcement of section 504.

OCR Investigations to Date

Another argument made by a number of commenters to support criticisms of the adequacy of the factual basis for the

proposed rule was that the experience of the Office for Civil Rights to date in connection with section 504 enforcement activities relating to health care for handicapped infants indicate there is no significant evidence of a problem that the rule could reasonably be designed to deal with. As stated by the American Hospital Association:

> The total absence of verifiable violations, notwithstanding hundreds of hotline calls, also compels the conclusion that either this mechanism is not an effective means to meet any alleged need or, as we believe to be the case, the violations that have been described are not occurring. In either case, a federal regulation is unnecessary.

Response

Rather than support the argument that there is no need for section 504 applicability or enforcement in connection with health care for handicapped infants, the OCR experience to date provides additional evidence that the assumption that handicapped infants will receive medically beneficial treatment is not always justified.

First, it must be noted that the vast majority of the several hundred calls made to the Department were not for the purpose of reporting suspected violations of section 504. Rather, the vast majority of calls were for administrative purposes, such as hospital officials asking questions about the provisions of the March interim final rule, individuals acting on their apparent curiosity to see if anyone would answer the telephone, and other peripheral matters. It should also be noted that the Department's experience under the interim final rule does not provide an adequate basis to make conclusive judgments in any direction because the rule was only in effect for about three weeks, from March 22 until April 14, the day Judge Gesell declared it invalid.

Following is a summary of the Infant Doe cases handled to date, and current as of December 1, 1983.

1. *Bloomington, Indiana.* Investigation into April 1982, death of infant with Down's syndrome and esophageal atresia from whom surgery was withheld on the instructions of the parents. An investigation, delayed due to difficulties in obtaining information sealed by court order, has been conducted. Final administrative action has not yet been taken.

2. *Robinson, Illinois.* May 14, 1982, complaint that hospital (at the parents' request) failed to perform necessary surgery on an infant born with myelomeningocele. Prompt on-site investigation was conducted, involving OCR, the Justice Department and the state child protective services agency. The parents refused consent for surgery; the hospital referred the matter to state authorities, who accepted custody of the infant and arranged for surgery and adoption. The care provided to the infant while these actions were taken was in compliance with section 504. Finding: no violation.

3. *Madison, Wisconsin.* May 7, 1982, complaint that two infant survivors of abortions may have been denied treatment. On-site investigation revealed that two infants, of 26 and 22 weeks gestation, were born alive following abortions; life-saving procedures were applied; neither infant could survive due to extreme prematurity. Finding: no violation.

4. *Kettering, Ohio.* July 26, 1982, complaint that an infant with spina bifida and hydrocephalus was not being treated. Immediate on-site investigation revealed that surgery to correct the spina bifida condition was not performed immediately because the infant had medical complications. Surgery was performed after the infant's condition stabilized. The hospital provided all proper treatment. Finding: no violation.

5. *Barrington, Illinois.* September 17, 1982, complaint that a multi-handicapped infant was not receiving needed treatment. Immediate on-site investigation determined that given the nature and severity of the problems, there were no procedures or services which could have been provided which might have changed or otherwise influenced the outcome for this infant, who died four days after birth. Finding: no violation.

6. *New Haven, Connecticut.* October 12, 1982, complaint (referred from the Department of Justice) that hospital engaged in a pattern and practice of denying medical treatment to handicapped infants. The complaint was included in a compliance review, already in progress. The investigation has been expanded to include several cases involving other Connecticut hospitals. The investigation, which has included review of hundreds of medical files, has not been completed.

7. *Tulsa, Oklahoma.* December 7, 1982, complaint that a baby was being deliberately dehydrated. Immediate on-site investigation determined that the infant had hydranencephaly (complete or almost complete absence of cerebral hemispheres) and transposition of the great vessels (reversal of main vessels into heart); notwithstanding all proper care, the severity of the anomalies made the prognosis very pessimistic. Finding: no violation.

8. *Duarte, California.* January 10, 1983, complaint that the hospital denied the complainant's son admission to the hospital for a bone marrow transplant solely because of his handicapping condition, Down's syndrome. An investigation has been conducted. Administrative action has not been completed.

9. *Austin, Texas.* January 17, 1983, complaint that newborn babies with serious birth defects have not received proper care. An investigation has been conducted. Administrative action has not been completed.

10. *Lansing, Michigan.* January 24, 1983, complaint that a handicapped infant born to a surrogate mother was treated for a streptococci infection over the objections of the father who had told the hospital not to care for the child. OCR inquiry determined the hospital took immediate steps to obtain an appropriate court order to assure that needed treatment was provided, notwithstanding objections from the father. Finding: no violation.

11. *San Antonio, Texas.* March 2, 1983, complaint that deaths of a number of infants at two hospitals may have been related to discriminatory withholding of care. OCR investigation postponed at request of District Attorney assisting in grand jury criminal investigation.

12. *Houston, Texas.* March 10, 1983, complaint that five infants were denied proper care in a neonatal intensive care unit. The investigation has not been completed.

13. *Jackson, Michigan.* March 14, 1983, complaint from a mother that her son, who had Down's syndrome, died as a result of improper treatment. An investigation has been conducted. Administrative action not completed.

14. *Odessa, Texas.* March 18, 1983, hotline complaint that the hospital had failed to provide adequate medical care to a

premature infant who died in 1982. On-site investigation and review of medical records by OCR medical consultant found that the infant, born March 18, 1982, after a 25-26-week gestation period, suffered from extreme immaturity, and died March 20, 1982. Finding: no violation.

15. *Nashville, Tennessee.* March 22, 1983, hotline complaint that an infant had been denied sustenance for three days. Immediate contact revealed the infant was not a patient at the facility and the alleged attending physician was not a member of the attending or resident medical staff. This was verified by the patient census data, the facility's physician roster, and contact with the county medical society. This case was administratively closed due to an insufficient complaint.

16. *Nashville, Tennessee.* March 22, 1983, anonymous hotline complaint that 10 children were not receiving adequate medical treatment. Immediate on-site investigation, including an OCR medical consultant, determined that no child was in imminent danger; all children were receiving nutritional sustenance; and all children were receiving proper care. Finding: no violation.

17. *Fayette, Alabama.* March 22, 1983, anonymous hotline complaint that a handicapped infant was denied nourishment and allowed to die in an Alabama hospital in December 1982. The caller could provide no other information. Investigation has been conducted. Administrative action awaiting report from medical consultant.

18. *Waxahachie, Texas.* March 23, 1983, anonymous hotline complaint that between Christmas and February, a premature infant was denied treatment and allowed to die at a hospital in Texas. An investigation has been conducted. Administrative action not yet completed.

19. *Baltimore, Maryland,* March 23, 1983, hotline complaint that a premature infant was not being provided nourishment and heat. An immediate on-site investigation determined that the infant, weight 1 lb., ½ ounce at birth, was previable; the infant died several hours after birth; the infant had no congenital malformations or anomalies. Final administrative action on this case has not yet been taken.

20. *Newark, New Jersey.* March 27, 1983, anonymous hotline complaint that a premature infant, born as a result of a third trimester abortion, was not receiving adequate care. Immediate on-site investigation revealed that the premature infant weighed about 700 grams, and showed few signs of life. The infant was aggressively resuscitated, placed on intravenous feeding, and provided other life supporting treatment. Appropriate care was being provided. Finding: no violation.

21. *Rochester, New York.* March 29, 1983, hotline complaint that Siamese twin infants were being denied treatment. Immediate on-site investigation determined that team specialists examined the infants and concluded the conjoined female infant would not survive any attempt to separate them. Full intensive care was provided. The infants were placed on a respirator and given antibiotics, fluid and the necessary nutrition. At the time of the on-site, March 29, 1983, it was determined that there was no basis for seeking emergency remedial action. Final administrative action has not yet been completed.

22. *Seattle, Washington.* March 30, 1983, hotline complaint that an infant was being denied food and water and would not live much longer than a day or two. The caller had no identifying or other information. Immediate on-site inquiry determined there were no infants at the facility meeting the description of the complaint. The case was administratively closed due to insufficient complaint.

23. *Miami, Florida.* April 4, 1983, hotline complaint alleging (based upon information in the newspaper) parents of a premature infant and the attending physician decided not to allow the infant to be resuscitated. Immediate inquiry determined the infant had died prior to receipt of the complaint. The premature infant had multiple catastrophic conditions, including complete liquefaction of the brain. Final administrative action awaiting report of medical consultant.

24. *Decatur, Alabama.* April 6, 1983, hotline complaint from a parent that her child's condition was misdiagnosed by a particular physician during a 2½ year period. Inquiry determined that the child suffers from food allergies; the prognosis is excellent, the child at one time was believed,

apparently erroneously, to be retarded. This case was administratively closed because the inquiry failed to reveal information suggesting a possible violation of section 504.

25. *Melrose Park, Illinois.* April 8, 1983, anonymous hotline complaint. The caller provided no details concerning the infant's condition or treatment. Immediate telephone inquiry discovered no information to suggest a section 504 violation. This case was administratively closed due to an insufficient complaint.

26. *Charlotte, North Carolina.* April 10, 1983, hotline complaint that a premature infant died in July 1979 due to withholding of treatment. The caller could not provide any other information. Due to the length of time since the alleged discriminatory act and the lack of specific information, this case was administratively closed due to an insufficient complaint.

27. *Hyde Park, New York.* April 13, 1983, anonymous hotline complaint that the hospital would have let a baby with Down's syndrome die if the parents had not been aggressive and insisted on care being provided. The caller could provide no identifying information. This case was administratively closed due to an insufficient complaint.

28. *Coquille, Oregon.* April 13, 1983, hotline complaint that parents of a handicapped infant and the attending physican were going to withhold all treatment. Immediate on-site investigation, including medical consultant's review of medical records, determined the infant had a severe congenital central nervous system defect incompatible with life and not amenable to surgical correction; hospital provided supportive care and attempted to provide fluid orally, but did not attempt to provide intravenous fluids or arrange immediate transfer to a tertiary level neonatal intensive care unit for more specialized evaluations. The OCR medical consultant and the specialists at the tertiary care facility to which the infant was transferred three days after birth concluded that no course of treatment which was available would have avoided imminent death of this infant; the most that could have been expected from more aggressive care would have been to prolong the act of dying. The infant died 10 days after birth. Finding: no violation.

29. *Athens, Tennessee.* April 18, 1983, anonymous hotline complaint that an infant born at 28 weeks gestation was denied treatment and nourishment and allowed to die at a Tennessee hospital. The caller could give no identifying information. Investigation has been conducted. Administrative action awaiting report of medical consultant.

30. *Shreveport, Louisiana.* April 20, 1983, hotline complaint that a particular physician at the hospital certified three infants born alive as stillborn and refused to provide care to another infant. Investigation, including medical consultant review, found no medically beneficial treatment was withheld. Finding: no violation.

31. *Dayton, Ohio.* April 29, 1983, anonymous hotline complaint that an infant, identity unknown, weighing one pound and eight ounces was denied treatment and died. Inquiry revealed the deceased infant was premature (22 weeks gestation) and immature (organs were not developed); the infant had no anomalies; the hospital attempted to administer oxygen but the lungs were too small to function; no medically benefical treatment was withheld. This case was administratively closed due to the lack of information suggesting possible violation of section 504.

32. *Los Angeles, California.* May 17, 1983, complaint that infant, believed stillborn, lived several hours and may not have received proper care. Administrative action has not been completed.

33. *Daytona Beach, Florida.* May 19, 1983, hotline complaint that an infant with spina bifida may not be receiving medical treatment. Immediate contact with hospital and state agency and prompt on-site investigation indicated that the parents did not consent to surgery for the infant; on May 18, eight days after birth, the state agency obtained a court order to provide surgery, which was performed May 22, 1983. An investigation has been conducted. Administrative action awaits report of medical consultant.

34. *Baton Rouge, Louisiana.* May 23, 1983, hotline complaint that medical services were denied a premature infant, who died soon after birth. Investigation has been conducted. Administrative action has not been completed.

35. *Colorado Springs, Colorado.* June 21, 1983, hotline complaint from a nurse that an infant with myelomeningocele and paralyzed vocal chords was being denied necessary surgery. Immediate on-site investigation indicated substantial uncertainty on whether treatment for the myelomeningocele would be provided immediately; physicians were providing nutrition and supportive care and were awaiting the results of several tests on the infant. During the afternoon, hospital personnel were advised that an on-site investigation would be initiated that evening; that the state child protective services agency would be asked to also investigate; and that OCR would notify the Justice Department of the investigation. Also during the afternoon, the OCR medical consultant discussed the case with the attending physician. That evening corrective surgery was performed on the myelomeningocele. Investigation, including review by medical consultant, determined that no medically beneficial treatment was withheld on the basis of the infant's handicap. Finding: no violation.

36. *Brooklyn, New York.* June 23, 1983, complaint that premature infant who died in 1981 did not receive proper care. An investigation was conducted. Administrative action awaits report of medical consultant.

37. *Atlanta, Georgia.* June 27, 1983, hotline complaint that an infant, identity unknown, born with multiple anomalies was in a life-threatening situation because the doctors were planning to cease treatment of the infant. On-site investigation, June 28, indicated the premature infant, who weighed 950 grams at birth, received aggressive treatment, but the prognosis was not optimistic. At the time of the on-site investigation, it was determined there was no basis to seek emergency remedial action. Final administrative action is awaiting written report from medical consultant.

38. *Medford, Oregon.* July 7, 1983, anonymous hotline complaint that two infants died in 1982 because of improper medical treatment. The investigation has not been completed.

39. *Pinehurst, North Carolina.* July 21, 1983, hotline complaint that a three-week old infant with spina bifida and hydrocephalus would not live if surgical treatment was not pro-

vided. Immediate inquiry determined the appropriate surgery was performed July 8, 1983. Final administrative action has not been concluded.

40. *San Francisco, California.* August 2, 1983, hotline complaint that an infant with a cleft palate and heart defect was allowed to die at a California hospital in May 1979. The caller stated that a malpractice lawsuit is pending. The investigation has not been completed.

41. *Falls Church, Virginia.* August 9, 1983, hotline complaint that a baby, identity unknown, with possible brain damage, no ears or eyes, would not be given nourishment. A meeting with hospital officials failed to identify an infant meeting the description given by the complainant. An infant with somewhat similar circumstances was described; no information concerning this infant suggested a lack of appropriate care. Complaint refused to accept OCR calls seeking further information. This case was administratively closed due to an insufficient complaint.

42. *Wichita, Kansas.* August 11, 1983, complaint that infant whose body was discovered at incinerator site may have been denied proper treatment. An investigation has been conducted. Administrative action has not been completed.

43. *Lincoln, Nebraska.* August 25, 1983, hotline complaint that two premature infants did not receive appropriate care and died. The investigation has not been completed.

44. *Boynton Beach, Florida.* September 20, 1983, hotline complaint that two handicapped infants were allowed to die immediately following birth. The investigation has not been completed.

45. *Norfolk, Virginia.* September 21, 1983, complaint that infant born alive following an abortion was not being fed or treated. Inquiry determined infant died September 20, 1983. Final administrative action has not been completed.

46. *Boise, Idaho.* September 30, 1983, hotline complaint that an abandoned premature infant with no brain tissue might be withdrawn from life support. Immediate inquiry determined the State child protective services agency had obtained custody of the infant and had no plans to discontinue life support. Final administrative action has not been completed.

47. *Philadelphia, Pennsylvania.* October 16, 1983, hotline complaint that infant, age approximately six weeks, with spina bifida, who received surgery, was not receiving appropriate follow-up care. Inquiry initiated October 16. Decision made that circumstances did not suggest need for immediate remedial action. Final administrative action has not been completed.

48. *Long Island, New York.* October 19, 1983, complaint, based on newspaper article, that infant with spina bifida not receiving surgery due to refusal of parents to consent; legal proceedings had been initiated in State court. Inquiry initiated October 19. On October 27, HHS asked Department of Justice to commence legal action to overcome refusal of hospital to permit review of pertinent records. On November 2, legal action was commenced. On November 17, district court ruled against the government. Appeal filed November 18.

49. *Phoenix, Arizona.* November 7, 1983, anonymous hotline complaint that infant with spina bifida and other conditions not receiving surgery. Immediate inquiry intiated; records obtained; OCR medical consultant discussed case with attending physician and hospital review committee. Decision made not to refer case to Justice Department for emergency remedial action. Final administrative action not yet completed.

The Department believes three of these cases demonstrate the utility of the procedural mechanisms called for in the final rules. In the Robinson, Illinois, case (listed as case 2, above), for example, the involvement of the state child protective services agency, working in cooperation with HHS and the Justice Department, was the most important element in bringing about corrective surgery for the infant. The state agency received a report from the hospital administrator pursuant to the state child protective services statute. Had there been no governmental involvement in the case, the outcome might have been much less favorable. Media reports one year later indicate the child's development was proceeding very well, with leg braces adequately compensating for the child's impairment.

In the Daytona Beach, Florida, case (listed as case 33, above), action by the state child protective services agency,

like that called for in the final rules, brought about needed corrective surgery. Without this action, the infant might have died or suffered more severe impairments.

In the Colorado Springs, Colorado, case (listed as case 35, above) the prompt involvement of HHS, acting upon a complaint from a nurse, may have contributed to the decision to provide corrective surgery. Because the decisionmaking process was in progress at the time the OCR inquiry began, it is impossible to say the surgery would not have been provided without this involvement. However, the involvement of OCR and the OCR medical consultant was cooperatively received by the hospital and apparently constructive.

Although no case has resulted in a finding of discriminatory withholding of medical care, the Department believes these cases provide additional documentation of the need for governmental involvement and the appropriateness of the procedures established by the final rules.

E. OTHER ISSUES

Self-Evaluation

Among the questions on which the July 5 notice of proposed rulemaking solicited comments was question 1:

> Should recipients providing health care services to infants be required to perform a self-evaluation, pursuant to 45 CFR 84.6(c)(1), with respect to their policies and practices concerning health services to handicapped infants?

A number of commenters expressed support for this requirement. Some commenters expressed the view that self-evaluations would be helpful and should be conducted, but they should not be a federal regulatory mandate. Some commenters suggested that if this were to be a requirement, it should be through mechanisms other than section 504, such as voluntary accreditation standards or Medicare conditions of participation.

Some commenters opposed a self-evaluation requirement on the grounds it would likely be unproductive. For example:

> Americans United for Life is skeptical of any approach to the enforcement of section 504 that relies on

the cooperation of those being regulated. Encouraging hospitals to perform "*self*-evaluation" is not likely to lead to *accurate* evaluation.

Response

The Department has not adopted a self-evaluation requirement as part of the final rules. The Department believes this function will be most effectively carried out in connection with the activities of Infant Care Review Committees encouraged by the final rules, and therefore will not seek to impose uniform standards for self-evaluations.

Information to Parents

Among the questions on which the July 5 notice of proposed rulemaking solicited comments was question 2:

> Should such recipients be required to identify for parents of handicapped infants born in their facilities those public and private agencies in the geographical vicinity that provide services to handicapped infants?

A great many commenters expressed support for such a requirement on the ground that before parents are put into a position of having to make very difficult decisions concerning care for their handicapped child, the parents should be aware of the health and social services agencies and organizations and parental support groups available in the community. Other commenters opposed this requirement. Some commenters expressed the view that hospitals should provide this information as part of their own policies and procedures, but that it would be counterproductive to seek to impose rigid, uniform regulatory requirements in this regard.

Among those supporting such a requirement was the Spina Bifida Association of America (SBAA):

> The SBAA strongly supports such a requirement; it might be the most important influential aspect of the entire regulation.
>
> Parents of a newborn spina bifida child are expected to make rational life and death decisions when what was expected to be a joyous time has instead become an occasion for confronting the concerns of the unknown. The decisions must be made quickly and under great stress.

> Dr. Rosalyn Darling, a member of SBAA's Professional Advisory Committee, has written that decisions are often made by physicians and individuals who have very little contact with the disabled community; consequently, decisions concerning treatment are often "stacked" against the newborn with a problem. Parents naturally turn to their physician for guidance, but he or she may have only outdated and unwarrantedly pessimistic information about spina bifida. Even if the physician is well-informed about the available treatment, he or she is rarely aware of the supportive services in the community or equipped to give the support and counselling that others who have gone through the same experience can't provide.
>
> Clearly, new parents of a disabled child need the names of agencies and support groups available to assist the family unit. Other parents who have gone through the same situation can then share their knowledge of the disability and its treatment and give comfort and assistance.

The American Speech-Language-Hearing Association, which represents 39,000 speech-language pathologists and audiologists nationwide, stated:

> [P]arents and physicians are largely unaware of what educational, habilitative, and rehabilitative services are available for handicapped children, how much success handicapped children receiving these services can have, the obligation of states to educate handicapped children, the extent of research now going on regarding handicapped children, and other federal, state and local governmental commitments to the handicapped. Unfortunately, physicians have all that they can do to maintain currency with medical information and are, therefore, frequently ill-informed as to what can be done for handicapped infants....
>
> * * * * *
>
> . .Recipients should be required to provide complete information to the parent about the appropriate handicap. This would include not only identification of public and private agencies that provide services to handicapped infants, but (1) detailed information on the handicap itself; (2) discussion of the educational and rehabilitation potential; (3) discussion of alternative care

> options such as foster homes, adoption, etc.; (4) identification of parent support groups; and (5) discussion of expectations for a self-sufficient future life. In providing the required information the recipient should use individuals knowledgeable about the handicap, including professionals, associations and parents of handicapped children. For example, the American Speech-Language-Hearing Association and its consumer affiliate, the National Association of Hearing and Speech Action (NAHSA) maintains a Help line (800-638-8255) that can be used to obtain information on (1) speech-language pathology and audiology services available in any area of the United States, (2) speech, language and hearing disorders, and (3) other agencies serving the communicatively handicapped. NAHSA provides informational brochures .... Many professional associations have similar documents that would be helpful to recipients.

Among those opposing a requirement that recipients provide information to parents was Georgetown University Hospital, Washington, D.C. As an alternative, the hospital proposed:

> DHHS should undertake the responsibility of providing a federal office charged with the task of identifying for parents of handicapped children those public and private agencies in the geographical vicinity of the parent's residence that provide service of handicapped infants, and for providing the necessary financial assistance to acquire such services. Hospitals should be required to furnish parents with a telephone number, and/or address of this federal office.

Response

The Department believes it is extremely important for parents of handicapped newborn infants to receive detailed information on the availability of health and social services for handicapped children in the communities. However, the Department has concluded the most effective way to advance this goal is not through an attempt to impose detailed regulatory requirements that would be very difficult to monitor and enforce.

Rather, the Department has undertaken several initiatives, discussed above in the preamble, to improve the furnishing of information to parents. In addition, this should be a central focus of the activities of the Infant Care Review Committees, which, under the model set forth in the final rules, include participation by representatives of disability groups or disability experts.

VI. Regulatory Information

Severability

It is the Secretary's intent that should any subsection, paragraph, clause, or provision of this rule be declared by a court of competent jurisdiction to be invalid, the remainder of the rule, not expressly so declared invalid, shall continue in effect.

Regulatory Impact Analysis

This proposed rule has been reviewed under Executive Order 12291. It is not a major rule as defined by the Order because it does not have an effect on the economy of $100 million or more or meet the other definitional criteria contained in the Order, and thus does not require a regulatory impact analysis.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act (Pub. L. 96-354) requires the Federal government to anticipate and reduce the impact of rules and paperwork requirements on small businesses and other small entities. For each rule with a "significant impact on a substantial number of small entities" an analysis must be prepared describing the rule's impact on small entities.

The Secretary certifies that the final rules do not have a significant impact on a substantial number of small entities. As it relates to hospitals, the primary requirement of the final rules is to post an informational notice, which has no significant impact on the hospitals. The requirements concerning expedited access to records and expedited action to effect compliance also, as explained above, have no significant impact. Requirements in the final rules relating to state child protective services agencies have no substantial impact

on those agencies, because those requirements, as explained above, are fully consistent with normal procedures of those agencies and existing regulatory requirements.

Matters addressed in the guidelines included in the final rules are not requirements of the rules. They reflect interpretations and procedures of the Department pursuant to the statute, existing regulations, and existing procedures.

Therefore, a regulatory flexibility analysis is not required.

Paperwork Reduction Act

Section 84.55(c) of the final rules contains information collection requirements. These requirements were submitted to the Office of Management and Budget for review under section 3504(h) of the Paperwork Reduction Act of 1980, and approved for use through September 30, 1986. The OMB No. is 0990-0114.

Department of Justice Review

Pursuant to Executive Order 12250, these final rules have been reviewed and approved by the Department of Justice.

List of Subjects in 45 CFR Part 84

Civil rights, Education of handicapped, Handicapped, Physically handicapped.

Dated: December 30, 1983.

Approved:

Margaret M. Heckler,

Secretary.

PART 84—[AMENDED]

The authority citation for Part 84 is as follows:

> **Authority:** Sec. 504, Rehabilitation Act of 1973, Pub. L. 93-112, 87 Stat. 394 (29 U.S.C. 794974) [*sic*]; sec. 111(a), Rehabilitation Act Amendments of 1974, Pub. L. 93-516, 88 Stat. 1619 (29 U.S.C. 706); sec. 606, Education of the Handicapped Act (20 U.S.C. 1405), as amended by Pub. L. 94-142, 89 Stat. 795; sec. 321, Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, 84 Stat. 182 (42 U.S.C. 4581), as amended; sec. 497, Drug Abuse Office and Treatment Act of 1972, 86 Stat. 78 (21 U.S.C. 1174), as amended.

For the reasons set forth in the preamble:

1. 45 CFR Part 84 is amended by inserting after § 84.54 the following new § 84.55:

§ 84.55 Procedures relating to health care for handicapped infants

(a) *Infant Care Review Committees.* The Department encourages each recipient health care provider that provides health care services to infants in programs receiving Federal financial assistance to establish an Infant Care Review Committee (ICRC) to assist the provider in delivering health care and related services to infants and in complying with this part. The purpose of the committee is to assist the health care provider in the development of standards, policies and procedures for providing treatment to handicapped infants and in making decisions concerning medically beneficial treatment in specific cases. While the Department recognizes the value of ICRC's in assuring appropriate medical care to infants, such committees are not required by this section. An ICRC should be composed of individuals representing a broad range of perspectives, and should include a practicing physician, a representative of a disability organization, a practicing nurse, and other individuals. A suggested model ICRC is set forth in paragraph (f) of this section.

(b) *Posting of informational notice.* (1) Each recipient health care provider that provides health care services to infants in programs or activities receiving Federal financial assistance shall post and keep posted in appropriate places an informational notice.

(2) The notice must be posted at location(s) where nurses and other medical professionals who are engaged in providing health care and related services to infants will see it. To the extent it does not impair accomplishment of the requirement that copies of the notice be posted where such personnel will see it, the notice need not be posted in area(s) where parents of infant patients will see it.

(3) Each health care provider for which the content of the following notice (identified as Notice A) is truthful may use Notice A. For the content of the notice to be truthful: (i) The provider must have a policy consistent with that stated in the notice; (ii) the provider must have a procedure for review of treatment deliberations and decisions to which the

notice applies, such as (but not limited to) an Infant Care Review Committee; and (iii) the statements concerning the identity of callers and retaliation are truthful.

Notice A:

PRINCIPLES OF TREATMENT OF DISABLED INFANTS

It is the policy of this hospital, consistent with Federal law, that nourishment and medically beneficial treatment (as determined with respect for reasonable medical judgments) should not be withheld from handicapped infants solely on the basis of their present or anticipated mental or physical impairments.

This Federal law, section 504 of the Rehabilitation Act of 1973, prohibits discrimination on the basis of handicap in programs or activities receiving Federal financial assistance. For further information, or to report suspected noncompliance, call:

[Identify designated hospital contact point and telephone number] or

[Identify appropriate child protective services agency and telephone number] or

U.S. Department of Health and Human Services (HHS): 800-368-1019 (Toll-free: available 24 hours a day; TDD capability).

The identity of callers will be held confidential. Retaliation by this hospital against any person for providing information about possible noncompliance is prohibited by this hospital and Federal regulations.

(4) Health care providers other than those described in paragraph (b)(3) of this section must post the following notice (identified as Notice B):

Notice B:

PRINCIPLES OF TREATMENT OF DISABLED INFANTS

Federal law prohibits discrimination on the basis of handicap. Under this law, nourishment and medically beneficial treatment (as determined with respect for reasonable medical judgments) should not be withheld from handicapped infants solely on the basis of their present or anticipated mental or physical impairments.

This Federal law, section 504 of the Rehabilitation Act of 1973, applies to programs or activities receiving

Federal financial assistance. For further information, or to report suspected noncompliance, call:

[Identify appropriate child protective services agency and telephone number] or

U.S. Department of Health and Human Services (HHS): 800-368-1019 (Toll-free: available 24 hours a day; TDD capability).

The identity of callers will be held confidential. Federal regulations prohibit retaliation by this hospital against any person who provides information about possible violations.

(5) The notice may be no smaller than 5 by 7 inches, and the type size no smaller than that generally used for similar internal communications to staff. The recipient must insert the specified information on the notice it selects. Recipient hospitals in Washington, D.C. must list 863-0100 as the telephone number for HHS. No other alterations may be made to the notice. Copies of the notices may be obtained from the Department of Health and Human Services upon request, or the recipient may produce its own notices in conformance with the specified wording.

(c) Responsibilities of recipient state child protective services agencies. (1) Within 60 days of the effective date of this section, each recipient state child protective services agency shall establish and maintain in written form methods of administration and procedures to assure that the agency utilizes its full authority pursuant to state law to prevent instances of unlawful medical neglect of handicapped infants. These methods of administration and procedures shall include:

(i) A requirement that health care providers report on a timely basis to the state agency circumstances which they determine to constitute known or suspected instances of unlawful medical neglect of handicapped infants;

(ii) A method by which the state agency can receive reports of suspected unlawful medical neglect of handicapped infants from health care providers, other individuals, and the Department on a timely basis;

(iii) Immediate review of reports of suspected unlawful medical neglect of handicapped infants and, where appropriate, on-site investigation of such reports;

(iv) Provision of child protective services to such medically neglected handicapped infants, including, where appropriate, seeking a timely court order to compel the provision of necessary nourishment and medical treatment; and

(v) Timely notification to the responsible Department official of each report of suspected unlawful medical neglect involving the withholding, solely on the basis of present or anticipated physical or mental impairments, of treatment or nourishment from a handicapped infant who, in spite of such impairments, will medically benefit from the treatment or nourishment, the steps taken by the state agency to investigate such report, and the state agency's final disposition of such report.

(2) Whenever a hospital at which an infant who is the subject of a report of suspected unlawful medical neglect is being treated has an Infant Care Review Committee (ICRC) the Department encourages the state child protective services agency to consult with the ICRC in carrying out the state agency's authorities under its state law and methods of administration. In developing its methods of administration and procedures, the Department encourages child protective services agencies to adopt guidelines for investigations similar to those of the Department regarding the involvement of ICRC's.

(The provisions of § 84.55(c) have been approved by the Office of Management and Budget pursuant to the Paperwork Reduction Act. The OMB No. is 0990-0114).

(d) *Expedited access to records.* Access to pertinent records and facilities of a recipient pursuant to 45 CFR 80.6(c) (made applicable to this part by 45 CFR 84.61) shall not be limited to normal business hours when, in the judgment of the responsible Department official, immediate access is necessary to protect the life or health of a handicapped individual.

(e) *Expedited action to effect compliance.* The requirement of 45 CFR 80.8(d)(3) pertaining to notice to recipients prior to the initiation of action to effect compliance (made applicable to this part by 45 CFR 84.61) shall not apply when, in the judgment of the responsible Department official, immediate action to effect compliance is necessary to protect

the life or health of a handicapped individual. In such cases the recipient will, as soon as practicable, be given oral or written notice of its failure to comply, of the action to be taken to effect compliance, and its continuing opportunity to comply voluntarily.

(f) *Model Infant Care Review Committee.* Recipient health care providers wishing to establish Infant Care Review Committees should consider adoption of the following model. This model is advisory. Recipient health care providers are not required to establish a review committee or, if one is established, to adhere to this model. In seeking to determine compliance with this part, as it relates to health care for handicapped infants, by health care providers that have an ICRC established and operated substantially in accordance with this model, the Department will, to the extent possible, consult with the ICRC.

(1) *Establishment and purpose.* (i) The hospital establishes an Infant Care Review Committee (ICRC) or joins with one or more other hospitals to create a joint ICRC. The establishing document will state that the ICRC is for the purpose of facilitating the development and implementation of standards, policies and procedures designed to assure that, while respecting reasonable medical judgments, treatment and nourishment not be withheld, solely on the basis of present or anticipated physical or mental impairments, from handicapped infants who, in spite of such impairments, will benefit medically from the treatment or nourishment.

(ii) The activities of the ICRC will be guided by the following principles:

(A) The interpretative guidelines of the Department relating to the applicability of this part to health care for handicapped infants.

(B) As stated in the "Principles of Treatment of Disabled Infants" of the coalition of major medical and disability organizations, including the American Academy of Pediatrics, National Association of Children's Hospitals and Related Institutions, Association for Retarded Citizens, Down's Syndrome Congress, Spina Bifida Association, and others:

> When medical care is clearly beneficial, it should always be provided. When appropriate medical care is

not available, arrangements should be made to transfer the infant to an appropriate medical facility. Consideration such as anticipated or actual limited potential of an individual and present or future lack of available community resources are irrelevant and must not determine the decisions concerning medical care. The individual's medical condition should be the sole focus of the decision. These are very strict standards.

It is ethically and legally justified to withhold medical or surgical procedures which are clearly futile and will only prolong the act of dying. However, supportive care should be provided, including sustenance as medically indicated and relief of pain and suffering. The needs of the dying person should be respected. The family also should be supported in its grieving.

In cases where it is uncertain whether medical treatment will be beneficial, a person's disability must not be the basis for a decision to withhold treatment. At all times during the process when decisions are being made about the benefit or futility of medical treatment, the person should be cared for in the medically most appropriate ways. When doubt exists at any time about whether to treat, a presumption always should be in favor of treatment.

(C) As stated by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research:

> This (standard for providing medically beneficial treatment) is a very strict standard in that it excludes consideration of the negative effects of an impaired child's life on other persons, including parents, siblings, and society. Although abiding by this standard may be difficult in specific cases, it is all too easy to undervalue the lives of handicapped infants; the Commission finds it imperative to counteract this by treating them no less vigorously than their healthy peers or than older children with similar handicaps would be treated.

(iii) The ICRC will carry out its purposes by:

(A) Recommending institutional policies concerning the withholding or withdrawal of medical or surgical treatments to infants, including guidelines for ICRC action for specific categories of life-threatening conditions affecting infants;

(B) Providing advice in specific cases when decisions are being considered to withhold or withdraw from infant life-sustaining medical or surgical treatment; and

(C) Reviewing retrospectively on a regular basis infant medical records in situations in which life-sustaining medical or surgical treatment has been withheld or withdrawn.

(2) *Organization and staffing.* The ICRC will consist of at least 7 members and include the following:

(i) A practicing physician (e.g., a pediatrician, a neonatologist, or a pediatric surgeon),

(ii) A practicing nurse,

(iii) A hospital administrator,

(iv) A representative of the legal profession,

(v) A representative of a disability group, or a developmental disability expert,

(vi) A lay community member, and

(vii) A member of a facility's organized medical staff, who shall serve as chairperson.

In connection with review of specific cases, one member of the ICRC shall be designated to act as "special advocate" for the infant, as provided in paragraph (f)(3)(ii)(E) of the section. The hospital will provide staff support for the ICRC, including legal counsel. The ICRC will meet on a regular basis, or as required below in connection with review of specific cases. It shall adopt or recommend to the appropriate hospital official or body such administrative policies as terms of office and quorum requirements. The ICRC will recommend procedures to ensure that both hospital personnel and patient families are fully informed of the existence and functions of the ICRC and its availability on a 24-hour basis.

(3) *Operation of ICRC—(i) Prospective policy development.* (A) The ICRC will develop and recommend for adoption by the hospital institutional policies concerning the withholding or withdrawal of medical treatment for infants with life-threatening conditions. These will include guidelines for management of specific types of cases or diagnoses, for example, Down's syndrome and spina bifida, and procedures to be followed in such recurring circumstances as, for example, brain death and parental refusal to consent to life-saving treatment. The hospital, upon recommendation

of the ICRC, may require attending physicians to notify the ICRC of the presence in the facility of an infant with a diagnosis specified by the ICRC, e.g., Down's syndrome and spina bifida.

(B) In recommending these policies and guidelines, the ICRC will consult with medical and other authorities on issues involving disabled individuals, e.g., neonatologists, pediatric surgeons, county and city agencies which provide services for the disabled, and disability advocacy organizations. It will also consult with appropriate committees of the medical staff, to ensure that the ICRC policies and guidelines build on existing staff by-laws, rules and regulations concerning consultations and staff membership requirements. The ICRC will also inform and educate hospital staff on the policies and guidelines it develops.

(ii) *Review of specific cases.* In addition to regularly scheduled meetings, interim ICRC meetings will take place under specified circumstances to permit review of individual cases. The hospital will, to the extent possible, require in each case that life-sustaining treatment be continued, until the ICRC can review the case and provide advice.

(A) Interim ICRC meetings will be convened within 24 hours (or less if indicated) when there is disagreement between the family of an infant and the infant's physician as to the withholding or withdrawal of treatment, when a preliminary decision to withhold or withdraw life-sustaining treatment has been made in certain categories of cases identified by the ICRC, when there is disagreement between members of the hospital's medical and/or nursing staffs, or when otherwise appropriate.

(B) Such interim ICRC meetings will take place upon the request of any member of the ICRC or hospital staff or parent or guardian of the infant. The ICRC will have procedures to preserve the confidentiality of the identity of persons making such requests, and such persons shall be protected from reprisal. When appropriate, the ICRC or a designated member will inform the requesting individual of the ICRC's recommendation.

(C) The ICRC may provide for telephone and other forms of review when the timing and nature of the case, as

identified in policies developed by the ICRC, make the convening of an interim meeting impracticable.

(D) Interim meetings will be open to the affected parties. The ICRC will ensure that the interests of the parents, the physician, and the child are fully considered; that family members have been fully informed of the patient's condition and prognosis; that they have been provided with a listing which describes the services furnished by parent support groups and public and private agencies in the geographic vicinity to infants with conditions such as that before the ICRC; and that the ICRC will facilitate their access to such services and groups.

(E) To ensure a comprehensive evaluation of all options and factors pertinent to the committee's deliberations, the chairperson will designate one member of the ICRC to act, in connection with that specific case, as special advocate for the infant. The special advocate will seek to ensure that all considerations in favor of the provision of life-sustaining treatment are fully evaluated and considered by the ICRC.

(F) In cases in which there is disagreement on treatment between a physician and an infant's family, and the family wishes to continue life-sustaining treatment, the family's wishes will be carried out, for as long as the family wishes, unless such treatment is medically contraindicated. When there is physician/family disagreement and the family refuses consent to life-sustaining treatment, and the ICRC, after due deliberation, agrees with the family, the ICRC will recommend that the treatment be withheld. When there is physician/family disagreement and the family refuses consent, but the ICRC disagrees with the family, the ICRC will recommend to the hospital board or appropriate official that the case be referred immediately to an appropriate court or child protective agency, and every effort shall be made to continue treatment, preserve the status quo, and prevent worsening of the infant's condition until such time as the court or agency renders a decision or takes other appropriate action. The ICRC will also follow this procedure in cases in which the family and physician agree that life-sustaining treatment should be withheld or withdrawn, but the ICRC disagrees.

(iii) *Retrospective record review.* The ICRC, at its regularly-scheduled meeting, will review all records involving withholding or termination of medical or surgical treatment to infants consistent with hospital policies developed by the ICRC, unless the case was previously before the ICRC pursuant to paragraph (f)(3)(ii) of this section. If the ICRC finds that a deviation was made from the institutional policies in a given case, it shall conduct a review and report the findings to appropriate hospital personnel for appropriate action.

(4) *Records.* The ICRC will maintain records of all of its deliberations and summary descriptions of specific cases considered and the disposition of those cases. Such records will be kept in accordance with institutional policies on confidentiality of medical information. They will be made available to appropriate government agencies, or upon court order, or as otherwise required by law.

Amendment to Table of Contents

2. The table of contents to 45 CFR Part 84 is amended by striking the designation of "84.55-84.60 [Reserved]" and by inserting in lieu thereof, the following:

Sec.
84.55 Procedures relating to health care for handicapped infants.
84.56-84.60 [Reserved]

3. 45 CFR Part 84 is amended by inserting after Appendix B the following new appendix:

Appendix C—Guidelines Relating to Health Care for Handicapped Infants.

(a) *Interpretative guidelines relating to the applicability of this part to health care for handicapped infants.* The following are interpretative guidelines of the Department set forth here to assist recipients and the public in understanding the Department's interpretation of section 504 and the regulations contained in this part as applied to matters concerning health care for handicapped infants. These interpretative guidelines are illustrative; they do not independently establish rules of conduct.

(1) With respect to programs and activities receiving Federal financial assistance, health care providers may not, solely on the basis of present or anticipated physical or mental impairments of an infant, withhold treatment or nourishment from the infant who, in spite of such impairments, will medically benefit from the treatment or nourishment.

(2) Futile treatment or treatment that will do no more than temporarily prolong the act of dying of a terminally ill infant is not considered treatment that will medically benefit the infant.

(3) In determining whether certain possible treatments will be medically beneficial to an infant, reasonable medical judgments in selecting among alternative courses of treatment will be respected.

(4) Section 504 and the provisions of this part are not applicable to parents (who are not recipients of Federal financial assistance). However, each recipient health care provider must in all aspects of its health care programs receiving Federal financial assistance provide health care and related services in a manner consistent with the requirements of section 504 and this part. Such aspects includes decisions on whether to report, as required by State law or otherwise, to the appropriate child protective services agency a suspected instance of medical neglect of a child, or to take other action to seek review or [sic] parental decisions to withhold consent for medically indicated treatment. Whenever parents make a decision to withhold consent for medically beneficial treatment or nourishment, such recipient providers may not, solely on the basis of the infant's present or anticipated future mental or physical impairments, fail to follow applicable procedures on reporting such incidents to the child protective services agency or to seek judicial review.

(5) The following are examples of applying these interpretative guidelines. These examples are stated in the context of decisions made by recipient health care providers. Were these decisions made by parents, the guideline stated in section (a)(4) would apply. These examples assume no facts or complications other than those stated. Because every case must be examined on its individual facts, these are merely illustrative examples to assist in understanding the framework for ap-

plying the nondiscrimination reuqirements of section 504 and this part.

(i) Withholding of medically beneficial surgery to correct an intestinal obstruction in an infant with Down's Syndrome when the withholding is based upon the anticipated future mental retardation of the infant and there are no medical contraindications to the surgery that would otherwise justify withholding the surgery would constitute a discriminatory act, violative of section 504.

(ii) Withholding of treatment for medically correctable physical anomalies in children born with spina bifida when such denial is based on anticipated mental impairment, paralysis or incontinence of the infant, rather than on reasonable medical judgments that treatment would be futile, too unlikely of success given complications in the particular case, or otherwise not of medical benefit to the infant, would constitute a discriminatory act, violative of section 504.

(iii) Withholding of medical treatment for an infant born with anencephaly, who will inevitably die within a short period of time, would not constitute a discriminatory act because the treatment would be futile and do no more than temporarily prolong the act of dying.

(iv) Withholding of certain potential treatments from a severely premature and low birth weight infant on the grounds of reasonable medical judgments concerning the improbability of success or risks of potential harm to the infant would not violate section 504.

(b) *Guidelines for HHS investigations relating to health care for handicapped infants.* The following are guidelines of the Department in conducting investigations relating to health care for handicapped infants. They are set forth here to assist recipients and the public in understanding applicable investigative procedures. These guidelines do not establish rules of conduct, create or affect legally enforceable rights of any person, or modify existing rights, authorities or responsibilities pursuant to this part. These guidelines reflect the Department's recognition of the special circumstances presented in connection with complaints of suspected life-threatening noncompliance with this part involving health care for handicapped infants. These guidelines do not apply to other investigations pursuant

to this part, or other civil rights statutes and rules. Deviations from these guidelines may occur when, in the judgment of the responsible Department official, other action is necessary to protect the life or health of a handicapped infant.

(1) Unless impracticable, whenever the Department receives a complaint of suspected life-threatening noncompliance with this part in connection with health care for a handicapped infant in a program or activity receiving Federal financial assistance, HHS will immediately conduct a preliminary inquiry into the matter by initiating telephone contact with the recipient hospital to obtain information relating to the condition and treatment of the infant who is the subject of the complaint. The preliminary inquiry, which may include additional contact with the complainant and a requirement that pertinent records be provided to the Department, will generally be completed within 24 hours (or sooner if indicated) after receipt of the complaint.

(2) Unless impracticable, whenever a recipient hospital has an Infant Care Review Committee, established and operated substantially in accordance with the provisions of 45 CFR 84.55(f), the Department will, as part of its preliminary inquiry, solicit the information available to, and the analysis and recommendations of, the ICRC. Unless, in the judgment of the responsible Department official, other action is necessary to protect the life or health of a handicapped infant, prior to initiating an on-site investigation, the Department will await receipt of this information from the ICRC for 24 hours (or less if indicated) after receipt of the complaint. The Department may require a subsequent written report of the ICRC's findings, accompanied by pertinent records and documentation.

(3) On the basis of the information obtained during preliminary inquiry, including information provided by the hospital (including the hospital's ICRC, if any), information provided by the complainant, and all other information obtained, the Department will determine whether there is a need for an on-site investigation of the complaint. Whenever the Department determines that doubt remains that the recipient hospital or some other recipient is in compliance with this part or additional documentation is desired to substantiate a conclu-

sion, the Department will initiate an on-site investigation or take some other appropriate action. Unless impracticable, prior to initiating an on-site investigation, the Department's medical consultant (referred to in paragraph 6) will contact the hospital's ICRC or appropriate medical personnel or the recipient hospital.

(4) In conducting on-site investigations, when a recipient hospital has an ICRC established and operated substantially in accordance with the provisions of 45 CFR 84.55(f), the investigation will begin with, or include at the earliest practicable time, a meeting with the ICRC or its designees. In all on-site investigations, the Department will make every effort to minimize any potential inconvenience or disruption, accommodate the schedules of health care professionals and avoid making medical records unavailable. The Department will also seek to coordinate its investigation with any related investigations by the state child protective services agency so as to minimize potential disruption.

(5) It is the policy of the Department to make no comment to the public or media regarding the substance of a pending preliminary inquiry or investigation.

(6) The Department will obtain the asistance of a qualified medical consultant to evaluate the medical information (including medical records) obtained in the course of a preliminary inquiry or investigation. The name, title and telephone number of the Department's medical consultant will be made available to the recipient hospital. The Department's medical consultant will, if appropriate, contact medical personnel of the recipient hospital in connection with the preliminary inquiry, investigation or medical consultant's evaluation. To the extent practicable, the medical consultant will be a specialist with respect to the condition of the infant who is the subject of the preliminary inquiry or investigation. The medical consultant may be an employee of the Department or another person who has agreed to serve, with or without compensation, in that capacity.

(7) The Department will advise the recipient hospital of its conclusions as soon as possible following the completion of a preliminary inquiry or investigation. Whenever final administrative findings following an investigation of a complaint of suspected life-threatening noncompliance cannot be made promptly, the Depart-

ment will seek to notify the recipient and the complainant of the Department's decision on whether the matter will be immediately referred to the Department of Justice pursuant to 45 CFR 80.8.

(8) Except as necessary to determine or effect compliance, the Department will (i) in conducting preliminary inquiries and investigations, permit information provided by the recipient hospital to the Department to be furnished without names or other identifying information relating to the infant and the infant's family; and (ii) to the extent permitted by law, safeguard the confidentiality of information obtained.

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[47 Fed. Reg. 26027 (June 16, 1982)]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Discriminating Against the Handicapped by Withholding Treatment or Nourishment, Notice of Health Care Providers

May 18, 1982

There has recently been heightened public concern about the adequacy of medical treatment of newborn infants with birth defects. Reports suggest that operable defects have sometimes not been treated, and instead infants have been allowed to die, because of the existence of a concurrent handicap, such as Down's syndrome.

This notice is intended to remind affected parties of the applicability of section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794). Section 504 provides that "No otherwise qualified handicapped individual * * * shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance * * *" Implementing regulations issued by the Department of Health and Human Services make clear that this statutory prohibition applies in the provision of health services [45 CFR 84.52] and that conditions such as Down's syndrome are handicaps within the meaning of section 504 (45 CFR 84.3 (j)).

Under section 504 it is unlawful for a recipient of Federal financial assistance to withhold from a handicapped infant nutritional sustenance or medical or surgical treatment required to correct a life-threatening condition, if:

(1) The withholding is based on the fact that the infant is handicapped; and

(2) The handicap does not render the treatment or nutritional sustenance medically contraindicated.

For example, a recipient may not lawfully decline to treat an operable life-threatening condition in an infant, or refrain from feeding the infant, simply because the infant is believed to be mentally retarded.

We recognize that recipients of Federal financial assistance may not have full control over the treatment of handicapped patients when, for instance, parental consent

has been refused. Nevertheless, a recipient may not aid or perpetuate discrimination by significantly assisting the discriminatory actions of another person or organization. 45 CFR 84.4(b)(1)(v). Recipients must accordingly insure that they do not violate section 504 by facilitating discriminatory conduct.

In fulfilling its responsibilities, a Federally assisted health care provider should review its conduct in the following areas to insure that it is not engaging in or facilitating discriminatory practices:

- Counseling of parents should not discriminate by encouraging parents to make decisions which, if made by the health care provider, would be discriminatory under section 504.
- Health care providers should not aid a decision by the infant's parents or guardian to withhold treatment or nourishment discriminatorily by allowing the infant to remain in the institution.
- Health care providers are responsible for the conduct of physicians with respect to cases administered through their facilities.

The failure of a recipient of Federal financial assistance to comply with the requirements of section 504 subjects that recipient to possible termination of Federal assistance. Moreover, section 504 does not limit the continued enforcement of State laws prohibiting the neglect of children, requiring medical treatment, or imposing similar responsibilities.

Betty Lou Dotson,
Director, Office for Civil Rights.

[FR Doc. 83-1825a Filed 6-14-82. 3:45 pm]
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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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84 CIV. 1724-CLB

AMERICAN MEDICAL ASSOCIATION,
a non-profit Illinois Corporation
535 North Dearborn Street
Chicago, Illinois 60610
(312) 645-5000,

AMERICAN HOSPITAL ASSOCIATION,
840 North Lake Shore Drive
Chicago, Illinois 60611
(312) 280-6000,

HOSPITAL ASSOCIATION OF NEW YORK STATE
15 Computer Drive West
Albany, New York 12205
(518) 458-7940,

AMERICAN COLLEGE OF OBSTETRICIANS
AND GYNECOLOGISTS
600 Maryland Avenue, S.W.
Suite 300-East
Washington, D.C. 20024
(202) 638-5577,

ASSOCIATION OF AMERICAN MEDICAL COLLEGES
One Dupont Circle, N.W.
Washington, D.C. 20036
(202) 828-0510,

AMERICAN ACADEMY OF FAMILY PHYSICIANS
1740 West 92d Street
Kansas City, Missouri 64114,

HUBERT A. RITTER, M.D.
1035 Bellevue, Suite 208
St. Louis, Missouri 63117
(314) 644-6262,

PETER A. M. AULD, M.D.
528 East 68th Street
New York, New York 10021
(212) 472-6874,

RITA GILMAN HARPER, M.D.
300 Community Drive
Manhasset, New York
(516) 562-4665,

ROY HOWARD PETRIE, M.D.
630 West 168 Street
New York, New York 10032
(212) 694-2818,
PLAINTIFFS,

-against-

MARGARET M. HECKLER, SECRETARY
DEPARTMENT OF HEALTH AND HUMAN SERVICES
330 Independence Avenue, S.W.
Washington, D.C. 20201
(202) 245-7000,
DEFENDANT.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Preliminary Statement

1. This action is brought on behalf of affected physicians and medical and other health care associations as representatives of their members. It seeks to declare invalid and permanently enjoin final rules on "Procedures and Guidelines Relating to Health Care for Handicapped Infants" [hereinafter "the Final Regulation"]. These rules were issued by the Secretary of the United States Department of Health and Human Services [hereinafter "HHS"] on January 12, 1984 and became effective on February 13, 1984. 49 Fed. Reg. 1621. The Final Regulation was promulgated under the putative authority of Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794. That statute proscribes discrimination against handicapped individuals under any program or activity receiving Federal financial assistance. This action also seeks to declare invalid and enjoin all investigation and enforcement actions which HHS is presently conducting and may in the future conduct under the putative authority of Section 504 with respect to alleged discrimination in treatment decisions involving impaired newborn infants.

2. This Final Regulation, and the other activities carried out by HHS under color of Section 504, involve direct Federal investigations, or Federally compelled state investigations, into one of the most sensitive, complex and personal areas in which parents must make decisions about their infant children in consultation with physicians: what sort of treatment, if any, should be given newborn infants suffering severe mental or physical impairment? This intrusion has recently been held unlawful by the United States Court of Appeals for the Second Circuit which ruled that Section 504 does not extend to treatment involving impaired newborn infants. *United States* v. *University Hospital*, No. 83-6343 (2nd Cir. February 23, 1984).

3. The Final Regulation requires all hospitals receiving Federal financial assistance to publish a uniform notice which improperly states that Section 504 applies to treatment decisions involving impaired newborns. This legally incorrect notice has the purpose and effect of stimulating complaints about parents' treatment decisions made on behalf of their children in consultation with their physicians. These complaints may be lodged with hospital, state or Federal authorities. The Final Regulation also requires physicians and other health professionals to violate their confidential relationship with parents as guardians of their patient children and to report to state child protection agencies "suspected instances" of "neglect" in parental decisions involving treatment of their impaired newborns. These state child protection agencies are, in turn, required by the Final Regulation to investigate all reports about parental treatment decisions involving impaired newborns, to invade confidential physician-patient records, and to intrude on the confidential physician-patient relationship by conducting interviews with the family's treatment team. The Final Regulation authorizes similar, duplicative Federal investigations into such treatment decisions. Finally, it uses Federal power to force state agencies to establish procedures for taking actions, according to state law processes and state law standards, that are aimed at removing the parent as ultimate treatment decision-maker for the impaired newborn—and it allows the Federal government to second-guess that state agency decision about whether or not to initiate actions against parents.

4. The Final Regulation and HHS' other investigations into treatment involving impaired newborns injure infants because medical personnel are diverted from provision of treatment to responding to investigations triggered without any standards. These HHS actions injure parents who are placed in tragic, stressful situations by vitiating their autonomy to make decisions for their children, subjecting them to improper investigations, violating their confidential relationship with physicians of their choice, and undermining their confidence in their physicians, in their hospitals and in the medical profession. These actions also injure physicians by forcing them to take actions under Federal dictates and standards that are inconsistent with medical practice, medical knowledge and medical ethics. Finally, HHS' actions injure recipients of Federal health care funds by forcing them to publish a legally incorrect notice which encourages harassing complaints about the patients in their facility and by requiring health care professionals in their employ to take actions which are inconsistent with medical practice, medical knowledge and medical ethics.

5. Both the Final Regulation and other enforcement activities by HHS under Section 504 are unlawful. They exceed the scope of authority granted to the Secretary of HHS by the Congress. Moreover, they constitute masive and unjustified invasions of the privacy rights of parents acting in the best interests of their impaired children in consultation with physicians of their choice. The Final Regulation is also unlawful as arbitrary and capricious agency action which constitutes an abuse of discretion and is not otherwise in accordance with law.

Jurisdiction and Venue

6. This action arises under Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. § 794); the Administrative Procedure Act (5 U.S.C. § 551 *et seq.*); and the First, Fifth and Ninth Amendments to the Constitution of the United States.

7. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331. This Court is authorized to issue appropriate declaratory relief under 28 U.S.C. §§ 2201-2202.

8. Venue is proper in this district under 28 U.S.C. § 1391.

Plaintiffs

9. Plaintiff American Medical Association [hereinafter "AMA"] is a national professional organization whose membership includes approximately 256,000 physicians, osteopaths and medical and osteopathic students. The AMA's membership includes over 10,000 pediatricians (of whom 294 are neonatalogists or perinatalogists) and over 14,000 obstetricians and gynecologists. These member physicians—in particular, pediatricians, obstetricians and gynecologists—practice their specialities in hospitals located in every state and the District of Columbia. The AMA's headquarters are in Chicago, Illinois, and the AMA maintains local offices in Washington, D.C. and New York, New York. The AMA is suing in its representative capacity on behalf of the thousands of physicians nationwide who will be affected by the challenged actions of Defendant. The AMA's purposes include promotion of quality patient care, protection of the ability of physicians to practice medicine according to their best professional judgment and protection of the confidentiality of the physician-patient relationship and of medical records.

10. Plaintiff American Hospital Association [hereinafter "AHA"] is a national organization whose membership includes approximately 6,000 of the nation's 7,000 hospitals. AHA is suing in its representative capacity on behalf of its members, the vast preponderance of which receive Federal financial assistance as defined in the Final Regulation. AHA's purposes include promotion of quality medical care provided to patients and protection of the confidentiality of medical records kept by health care providers for individual patients.

11. Plaintiff Hospital Association of New York State [hereinafter "HANYS"] is a not-for-profit association whose membership includes approximately 300 non-profit voluntary and public hospitals and health care institutions located in New York State. The vast preponderance of its members receive Federal financial assistance as defined in the Final Regulation, and HANYS is suing in its representative capacity on their behalf. HANYS' purposes include promoting

quality of care provided to patients and maintaining the confidentiality of medical records kept by health care providers for individual patients.

12. Plaintiff American College of Obstetricians and Gynecologists [hereinafter "ACOG"] is a private, voluntary, not-for-profit organization of physicians specializing in obstetrics and gynecology. ACOG's membership includes over 24,000 physician members representing approximately 90 percent of American obstetricians and gynecologists. ACOG is suing in its representative capacity on behalf of these thousands of obstetricians and gynecologists nationwide who will be affected by the challenged actions of Defendant. ACOG's purposes include promotion of high quality patient care in the field of obstetrics and gynecology, protection of confidential physician-patient relationships, and development of professional standards for the practice of obstetrics and gynecology.

13. Plaintiff Association of American Medical Colleges [hereinafter "AAMC"] is a national professional organization whose membership includes approximately 127 medical schools, 400 teaching hospitals and 76 academic societies in the United States. AAMC is suing in its representative capacity on behalf of its members, the vast preponderance of which receive Federal financial assistance as defined in the Final Regulation or which represent physicians who practice medicine in institutions that receive Federal financial assistance as defined in the Final Regulation. AAMC's purposes include the advancement of medical education and the improvement of health care in the United States.

14. Plaintiff American Academy of Family Physicians [hereinafter "AAFP"] is a national professional association whose membership includes approximately 56,000 family physicians and medical students. AAFP is suing in its representative capacity on behalf of these thousands of family physicians and medical students nationwide who will be affected by the challenged actions of Defendant. AAFP's purposes include promotion of excellence in health care and in the delivery and care of newborn infants.

15. Plaintiff Hubert A. Ritter, M.D., is a practicing obstetrician/gynecologist. He is Secretary-Treasurer of the

AMA. He is a member of the medical staffs of St. Louis University Hospital, St. Mary's Health Center and Deaconness Hospital. These health care institutions receive Federal financial assistance as defined in the Final Regulation. He is a Clinical Professor at St. Louis University's School of Medicine in the Department of Obstetrics and Gynecology.

16. Plaintiff Rita Gilman Harper, M.D., is a practicing neonatalogist. She is Chief of the Division of Perinatal Medicine at North Shore University Hospital in Manhasset, New York, and is a consultant in Perinatal Medicine at several other hospitals in the New York area. These hospitals receive Federal financial assistance as defined in the Final Regulation. She is Associate Professor of Pediatrics and Obstetrics and Gynecology at Cornell University Medical College, and is a member of the AMA, the American Pediatric Society and the American Academy of Pediatrics.

17. Plaintiff Peter A. M. Auld, M.D., is a practicing neonatalogist. He is Director of the Perinatalogy Center at New York Hospital in New York, New York. New York Hospital receives Federal financial assistance as defined in the Final Regulation. He is a member of the AMA, ACOG and the American Academy of Pediatrics.

18. Plaintiff Roy Howard Petrie, M.D., is a practicing obstetrician/gynecologist. He is Associate Professor of Obstetrics and Gynecology (Maternal Fetal Medicine) and Director of Obstetrical and Gynecological Education at the College of Physicians and Surgeons of Columbia University at the Columbia-Presbyterian Medical Center. This health care institution receives Federal financial assistance as defined in the Final Regualtion. He is a member of the AMA, ACOG, and the New York Obstetrical Society. He is President of the New York Perinatal Society and the Society of Perinatal Obstetricians.

Defendant

19. Defendant Margaret M. Heckler [hereinafter "Defendant"] is Secretary of the United States Department of Health and Human Services. As Secretary of HHS, she is the Federal official responsible for promulgation and imple-

mentation of the Final Regualtion and for other conduct which are the subjects of this action.

Regulatory and Judicial Background

20. The Final Regulation is promulgated pursuant to Section 504 of the Rehabilitation Act of 1973, Pub. L. No. 93-112, as amended in 1974, Pub. L. No. 93-516. Extensive Section 504 regulations were promulgated in 1977, 42 Fed. Reg. 22676 (May 4, 1977) (codified at 45 C.F.R. Part 84). Neither the statute nor the legislative and regulatory history evidence any intent to apply Section 504 to individual treatment decisions involving impaired newborn infants.

21. *Initial Notice.* On May 18, 1982, Defendant issued a "notice" to health care providers "to remind affected parties of the applicability of section 504 of the Rehabilitation Act of 1973." 47 Fed. Reg. 26027 (June 16, 1982) [hereinafter "Notice"]. The Notice stated that Section 504 made it unlawful for hospitals receiving Federal financial assistance to withhold from handicapped infants nutritional sustenance or medical or surgical treatment if required to correct a life-threatening condition. That Notice has not been explicitly rescinded or modified.

22. *Interim Final Rule.* On March 7, 1983, HHS promulgated, with only 15 days' notice, an "interim final rule" based on Section 504 concerning nondiscrimination on the basis of handicap. 48 Fed. Reg. 9630 (March 7, 1983). The rule required all hospitals which receive Federal financial assistance to post conspicuously in each delivery ward, maternity ward, pediatric ward, nursery, and intensive care nursery a notice stating that "DISCRIMINATORY FAILURE TO FEED AND CARE FOR HANDICAPPED INFANTS . . . IS PROHIBITED BY FEDERAL LAW." The notice advised further that "[*a*]*ny person having knowledge that a handicapped infant is being discriminatorily denied food or customary medical care should immediately contact:* Handicapped Infant Hotline. . . ." Telephone complaints received via the 24-hour, toll-free "hotline" were to be investigated and pursued in most cases by state child protective agencies. Regardless of actions by state agencies, the interim final rule authorized HHS: (a) to conduct immediate investiga-

tions, and (b) to make immediate referrals to the Department of Justice "for such legal action as may be necessary to save the life of a handicapped child...." When deemed necessary by an unidentified "responsible Department official," access to the facility itself and to the "pertinent records" would have had to be provided even outside of normal business hours.

23. *Invalidation of Interim Final Rule.* On April 14, 1983, the United States District Court for the District of Columbia declared the interim final rule invalid due to Defendant's violations of the Administrative Procedure Act. *American Academy of Pediatrics* v. *Heckler*, 561 F. Supp. 395 (D.D.C. 1983).

24. *HHS Enforcement Activities.* The ruling by the United States District Court for the District of Columbia did not enjoin HHS investigations and other enforcement activities undertaken pursuant to Section 504 with respect to treatment involving impaired newborn infants. Many complaints and reports received by HHS were in response to the May 18, 1982 Notice, which was also not affected by the District Court's decision. As of December 1, 1983, HHS' Office for Civil Rights had investigated, was investigating or had under consideration 49 complaints relating to treatment decisions involving impaired newborns. None of these actions had resulted in a finding of discriminatory withholding of treatment. A number of investigations or other enforcement actions undertaken by HHS before promulgation of the Final Regulation are still pending.

25. *Proposed Rule.* On July 5, 1983, HHS issued a proposed rule. The proposed rule still required establishment of a 24-hour "hotline" in hospitals and the posting of signs warning that withholding certain treatment from impaired newborn infants violated Section 504. State child protective agencies were required, under the proposal, to develop written rules and investigation procedures for handling "suspected cases of medical neglect of handicapped infants," although, as was the case with the invalidated interim final rule, it was contemplated that HHS itself "would closely monitor all investigation and enforcement activity taken pursuant to complaints."

26. *Final Regulation.* On January 12, 1984, HHS promulgated the Final Regulation which became effective on February 13, 1984 and which is challenged in this action. In most material respects, it is the same as or similar to the Interim Final Rule and to the Proposed Rule. *See* ¶¶ 29-33, *infra.*

27. Plaintiffs have exhausted all available administrative remedies which could provide the relief sought by this action.

28. *Second Circuit Decision.* On February 23, 1984, the United States Court of Appeals for the Second Circuit affirmed a decision by the United States District Court for the Eastern District of New York which refused to grant HHS access to medical records of an impaired newborn infant whose parents had decided not to authorize certain surgery. *United States* v. *University Hospital*, No. 83-6343 (2nd Cir. February 23, 1984). Defendant had sought the records in the fall of 1983, after the interim final rule was voided and before promulgation of the Final Regulation. In its opinion, the Court of Appeals held broadly that Section 504 did not apply to "treatment decisions involving defective newborn infants."

The Final Regulation: Provisions, Procedures and "Standards"

29. The Final Regulation has four mandatory provisions.

30. *Notice.* Section 84.55(b) requires each recipient health care provider that provides health services to infants in programs or activities receiving Federal financial assistance to post a notice, where nurses and other health care professionals will see it, which states, in part, that Section 504 prohibits discrimination on the basis of handicap and that under Section 504:

> nourishment and medically beneficial treatment (as determined with respect for reasonable medical judgments) should not be withheld from handicapped infants solely on the basis of their present or anticipated mental or physical impairments.

The required notice must include telephone numbers for a hospital contact point, the appropriate state child protective agency and a 24-hour a day HHS hotline where any person may call "to report suspected non-compliance" with the pre-

viously stated dictate of Section 504. There are no requirements that the person lodging a report have medical background or knowledge or have any direct personal knowledge of the particular course of treatment.

31. *State Agencies.* Section 84.55(c) provides that state child protective agencies which are recipients of Federal funds shall, within 60 days of the effective date of the Final Regulation, establish and maintain in written form "methods of administration and procedures to assure that the agency utilizes its full authority pursuant to state law to prevent instances of unlawful medical neglect of handicapped infants." All states have such agencies. These "methods and procedures" include a requirement that physicians and other health care providers must report on a timely basis to the state agency "circumstances which they determine to constitute known or suspected instances of unlawful medical neglect of handicapped infants." These state agencies must also establish procedures for receiving such reports, reviewing them, conducting on-site investigations and "seeking a timely court order to compel the provision of necessary nourishment and medical treatment." The state agencies must also establish procedures for informing HHS of each report of "suspected medical neglect," the steps taken to investigate such report and the state agency's final disposition of such report. Altnough the state agencies have 60 days in which to establish such written procedures, they have a present obligation to handle all "reports" of "medical neglect" from anonymous individuals, health professionals or HHS regarding treatment of impaired newborns, and health professionals have a present obligation to make such reports.

32. *HHS Investigations.* Section 84.55(d) authorizes HHS to have a 24-hour a day access to pertinent medical records and facilities. HHS may conduct an on-site investigation any time a responsible departmental official determines that immediate action is necessary to protect the life or health of an infant.

33. *Expedited Compliance Actions.* Section 84.55(e) authorizes HHS to take expedited action against recipients of Federal financial assistance to effect compliance with Section 504, including action by the Department of Justice, without providing notice to such recipients, if, in the judgment of the

responsible Department official, such action is necessary to protect the life or health of an infant.

34. None of the mandatory provisions of the Final Regulation have a basis in fact or are designed to meet a documented problem. HHS did not consider all the relevant factors before intruding into the sensitive area of individual treatment decisions involving impaired newborns. The Final Regulation is also devoid of any comprehensible standards or procedural safeguards regarding, *inter alia:* who may file reports; when it is appropriate or required to file such reports; what sort of evidence triggers an investigation; what qualifications shall be possessed by the person who decides to investigate; how investigations shall be carried out; what shall be investigated; who shall determine if proceedings shall be brought against parents; what standards shall govern such a decision; what standards shall govern a Federal decision that a state agency did not investigate properly or did not appropriately proceed against a parent; what standards shall govern a Federal decision that a recipient or physician or other provider did not properly report an instance of "known or suspected" medical neglect.

Injury

35. The allegations of paragraph 1 to paragraph 34 are incorporated by reference herein and realleged by reference.

36. Plaintiff physicians and medical and other health care organizations have suffered, are presently suffering and are imminently threatened with irreparable injuries as a result of HHS' Final Regulations and its unlawful application of Section 504 to treatment involving impaired newborn infants.

37. These past, present or threatened irreparable injuries are suffered directly by Plaintiff physicians and medical and other health care organizations; these injuries are the direct result of Defendant's interpretation of, and actions under, Section 504 with respect to the regulation of treatment involving impaired newborns; and the injuries will be redressed, or the threat of injury will be removed, by a favorable decision in this action. Plaintiffs' affidavits, which are attached to the memorandum in support of Plaintiff's motion for preliminary injunction, are incorporated by reference herein.

38. Parents, expectant parents and parents of impaired newborns generally, who have ultimate authority to act in the best interests of their children, and whose interests are appropriately asserted in this action by the physician Plaintiffs, are injured as a result of HHS' application of Section 504 to treatment decisions involving impaired newborn infants and as a result of the Final Regulation because, *inter alia:*

a. They have been, are or are threatened with being, the subject of "reports" lodged with hospitals, state authorities or HHS by third parties who have no medical training or medical knowledge, who have no direct personal knowledge of the facts of treatment decisions made by parents involving their impaired newborns and who do not realize that, contrary to the required notice provision of the Final Regulation, Section 504 does not apply to treatment decisions about impaired newborn infants;

b. They have been or are the subject of intrusive Federal or Federally compelled state investigations into their decisions involving the treatment of their impaired newborns, including invasion of their confidential relationship with their child's physicians and with other treating health professionals; or they are threatened with such investigations; and such intrusive investigations have occurred, are occurring or will occur when parents are in the middle of an anguishing decision-making process on behalf of their children;

c. They have suffered, are suffering or are threatened with suffering violations of their confidential relationship with the impaired infants' physicians and with other treating health professionals who are by Federal law required to report to state authorities cases of "known" or "suspected" parental neglect under vague and uncertain federal "neglect" standards;

d. They have been, are or will be at risk of Federally coerced actions by state authorities which challenge their fitness to make treatment decisions involving their impaired newborns;

e. They have suffered or are suffering distress, anxiety and fear at the widely publicized application by HHS of Section 504 to parents' individual treatment decisions on behalf

of their impaired newborn infants; at HHS's failure to define unlawful discrimination and neglect in a way that they or their physicians can understand; at the uncertainty which HHS's action has created for their confidential relationship with health professionals and for their confidence that health professionals are acting in the interest of their child; and this distress, anxiety or fear intrudes on their private decision-making and thus harms their infant children; and

f. They have suffered, are suffering or are threatened with suffering diminished quality of medical care for their newborn infants.

39. Physician Plaintiffs Hubert A. Ritter, Peter A. M. Auld, Rita Gilman Harper and Roy Howard Petrie are injured as a result of HHS' application of Section 504 to treatment decisions involving impaired newborn infants and as a result of the Final Regulation because, *inter alia:*

a. They are being subjected to legal duties regarding medical decisions under Federal regulatory standards—*e.g.*, "solely qualified," "discrimination," "medically beneficial treatment" and "medical neglect"—that have no clearly accepted or understood meaning with respect to the treatment of newborns with serious mental or physical impairments given the present state of medical knowledge;

b. They are being subjected to potentially inconsistent legal duties because "discrimination" and "medical neglect" as used in the May 18, 1982 Notice and in the Final Regulation are not susceptible of definition given the state of present medical knowledge and have a unique Federal meaning that is at odds with, or not yet recognized under, state law definitions which create physicians' legal obligations;

c. They have been, are or will be required to violate their confidential relationship with the parents of a seriously newborn child by responding to investigations of "reports" of medical neglect filed by third parties who lack medical training or knowledge or who lack direct personal knowledge of the treatment decisions made by parents in consultation with physicians;

d. They have been, are or will be injured in their ability to exercise professional medical judgment in the best interests of their patients;

e. They are threatened with being required to violate their confidential relationship with the parents of an impaired newborn child by the Federally imposed mandate that they "report" instances of "medical neglect" by parents when the standards governing such a duty is vague or at odds with medical practice and knowledge; and

f. Their impaired newborn patients, and the parents acting in the best interests of those patients, suffer injuries like those described in paragraph 38, incorporated by reference herein, and the physician Plaintiffs seek to protect such patients and parents from such injuries.

40. Plaintiff American Medical Association ("AMA") is injured, in its capacity of representative of 256,000 American physicians, as a result of HHS' application of Section 504 to treatment decisions involving impaired newborn infants and as a result of the Final Regulation because, *inter alia:*

a. The injuries suffered by the individual named physicians are typical of the injuries which the AMA's relevant member physicians across the nation will suffer as a result of HHS' policies, actions and regulations which have nationwide application and effect, and paragraph 39 is incorporated by reference herein and realleged;

b. The physician interests implicated by HHS' action are germane to the AMA's purposes which are, *inter alia*, to improve the quality of care to patients, including impaired newborn infants, and to protect the confidentiality of medical records and the doctor-patient relationship; and

c. The injuries suffered by the individual named physicians are illustrative of the injuries that all affected members of the AMA will suffer nationwide and the relief requested does not require participation of individual physicians in this action.

41. Plaintiff American College of Obstetricians and Gynecologists ("ACOG") is injured, in its capacity as representative of 24,000 American obstetricians and gynecologists, as a result of HHS' application of Section 504 to treatment decisions involving impaired newborn infants and as a result of the Final Regulation because, *inter alia*:

a. The injuries suffered by the Physician Plaintiff Peter A. M. Auld are typical of the injuries which ACOG's rele-

vant member physicians across the nation will suffer as a result of HHS' policies, actions and regulations which have nationwide application and effect, and paragraph 39 is incorporated by reference herein and realleged;

b. The physician interests implicated by HHS's action are germane to ACOG's purposes, which are, *inter alia*, to improve the quality of care to patients, including impaired newborn infants, and to protect the confidentiality of medical records and the doctor-patient relationship; and

c. The injuries suffered by the individual named physician is illustrative of the injuries that all affected members of ACOG will suffer nationwide and the relief requested does not require participation of individual physicians in this action.

42. Plaintiff American Academy of Family Physicians ("AAFP") is injured, in its capacity as representative of 56,000 American family physicians and medical students, as a result of HHS' application of Section 504 to treatment decisions involving impaired newborn infants and as a result of the Final Regulation because, *inter alia:*

a. The injuries suffered by the individual named physicians are typical of the injuries which AAFP's relevant member physicians across the nation will suffer as a result of HHS' policies, actions and regulations which have nationwide application and effect, and paragraph 39 is incorporated by reference herein and realleged;

b. The physician interests implicated by HHS' action are germane to AAFP's purpose which are, *inter alia*, to promote excellence in health care and in the delivery and care of newborn infants; and

c. The injuries suffered by the individual named physicians are illustrative of the injuries that all affected members of AAFP will suffer nationwide and the relief requested does not require participation of individual physicians in this action.

43. Plaintiffs American Hospital Association ("AHA"), Hospital Association of New York State ("HANYS") and Association of American Medical Colleges ("AAMC") are injured as a result of HHS' application of Section 504 to treat-

ment decisions involving impaired newborn infants and as a result of the Final Regulation because, *inter alia:*

a. Their member hospitals are required to post a notice which is inaccurate because Section 504 does not apply to treatment involving impaired newborn infants and which describes legal duties for their employees and medical staffs regarding medical decisions that have no accepted or understood meaning with respect to treatment involving impaired newborns given the present state of medical practice and knowledge;

b. The required notice, which is widely known by parents of newborns because of national publicity and which is likely to be brought to their attention within a hospital, will cause fright and anxiety in such parents and will lessen their confidence in hospitals and in the practice of medicine within hospitals;

c. Staff and employees within their member hospitals have been or are required to violate confidentiality requirements by responding to "reports" of medical neglect filed by third parties who lack medical training or knowledge or who lack direct personal knowledge of the treatment decisions made by parents in consultation with physicians;

d. Their member hospitals are required to force their staffs to report "suspected" instances of parental neglect to state agencies in violation of confidentiality requirements; and

e. Their member hospitals will be subjected to Federal investigations and compliance actions which are triggered without appropriate standards or due process safeguards.

COUNT I: Violation of Statutory Mandates

44. The allegations of paragraphs 1 through 43 are incorporated herein and realleged by reference.

45. Defendant's Final Regulation, her implementation of the Regulation and her other investigation and enforcement activities under Section 504 with respect to treatment involving newborn infants are unlawful as beyond the statutory authority of Section 504 because, *inter alia:*

a. Congress did not intend Section 504 to regulate treatment of impaired newborn infants;

b. Congress did not intend Section 504 to regulate directly or indirectly parental autonomy or treatment decision-making involving their impaired newborn infants;

c. Congress did not intend that newborns with serious mental or physical impairments be an "otherwise qualified" handicapped individual who may thus suffer "discrimination" in treatment decisions within the meaning of Section 504;

d. Congress did not intend that hospitals and physicians would have to undertake affirmative obligations with respect to impaired newborn infants; and

e. Congress did not intend that the Medicare and Medicaid programs would constitute Federal financial assistance to hospitals for purposes of triggering application of Section 504 to treatment decisions involving impaired newborn children; nor did Congress intend that, if Medicare and Medicaid are such assistance, this fact triggers application of Section 504 to all treatment decisions made by recipients' employees or staff in recipients' activities which do not receive Federal assistance.

COUNT II: Violation of the Administrative Procedure Act

46. The allegations of paragraphs 1 to 45 are incorporated herein and realleged by reference.

47. In promulgating the Final Regulation, Defendant has acted in an arbitrary and capricious manner, abused her discretion, taken actions otherwise not in accordance with the law and thus violated Section 10(e) of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), because, *inter alia:*

a. Defendant failed to demonstrate any factual basis for the Final Regulation because there are no instances cited where "erroneous" treatment decisions were made by parents *and* where hospitals or physicians did not seek protective orders from state agencies and because there is no evidence of actual cases where hospitals and physicians act differently with respect to handicapped and non-handicapped children in terms of reporting cases of abuse and neglect to state child protective agencies;

b. Defendant failed to describe or to survey present procedures employed by hospitals and other health care providers to protect impaired newborns if parents are deemed by

such hospitals and providers to be incapable of making decisions or to explain why such procedures are inadequate;

c. Defendant failed adequately to address the harmful effects of the regulation on impaired newborn infants themselves, ignoring probative evidence that the investigations mandated by the regulation have disrupted and will disrupt on-going treatment of impaired infants;

d. Defendant similarly failed to take adequate account of the far-reaching impact of the Final Regulation on parents, physicians and hospitals;

e. Defendant failed systematically to survey state child neglect law, to report any findings of such survey and to analyze the possible contradictions or inconsistencies between the Final Regulation's definition of "discrimination" and "medical neglect" and the standards for child neglect under state laws, and the effect on recipients and providers of these contradictions or inconsistencies;

f. Defendant failed to respond to significant comments and proposals made during the rulemaking proceeding; and

g. Defendant failed to show that the specific regulatory approach chosen bears a rational relationship to the objectives adopted by Defendant.

COUNT III: Violation of Privacy Rights Guaranteed by the Constitution and by Statute

48. The allegations of paragraphs 1 through 47 are incorporated herein and realleged by reference.

49. Defendant's Final Regulation, her implementation of the Regulation and her investigations and other enforcement activities under Section 504 with respect to medical decisions involving treatment of impaired newborn infants are unlawful as violative of parents' constitutional right of privacy to make fundamental personal decisions affecting family and children free from government interference because, *inter alia*:

a. Defendant's actions massively intrude on parents' right to make autonomous treatment decisions on behalf of their infant children;

b. Defendant's actions massively intrude on the parents' corollary right in making such decisions to consult fully and freely with physicians and to have physicians' ability to make

their best medical judgments be unimpeded by governmental interference; and

c. Defendant's actions injuring parents' constitutional rights are not justified by the requisite Federal interest.

50. Defendant's Final Regulation, her implementation of the Regulation and her investigations and other enforcement activities under Section 504 with respect to treatment involving impaired newborns are unlawful as violative of parents' constitutional and statutory rights of privacy to have personal matters free from disclosure because, *inter alia:*

a. Investigations into parents' sensitive personal and family medical matters and decisions about treatment have been or will be triggered without any standards and without adequate procedural safeguards;

b. Physicians and other health professionals have been or will be forced to violate ethical and statutory dictates in responding to such inappropriate investigations and to divulge confidential information about parents and their impaired newborn child; and

c. Hospitals and their employees have been or will be forced to violate ethical and statutory dictates in providing sensitive and confidential medical records containing information about parents and their impaired newborn child in response to such inappropriate investigations.

PRAYER FOR RELIEF

Plaintiffs respectfully request the following relief:

1. Defendant's Final Regulation on "Procedures and Guidelines Relating to Health Care for Handicapped Infants" should be declared invalid as exceeding the scope of Defendant's authority under Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794; as violating the requirements of the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*; as violating constitutional and statutory rights of privacy; and thus as having no further force and effect.

2. Defendant, her officers, agents, employees and attorneys should be permanently enjoined from any further implementation of the Final Regulation with respect to any program or activity receiving Federal financial assistance in any state, as defined in 29 U.S.C. § 706(14);

3. Defendant's other actions to regulate treatment involving impaired newborn infants taken under authority of Section 504, including currently pending investigation and other enforcement actions, should be declared unlawful as exceeding the scope of Defendant's authority under Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794; as violating constitutional and statutory rights of privacy; as thus having no further force and effect; and Defendant, her officers, agents, employees and attorneys should be permanently enjoined from continuing such actions with respect to any program or activity receiving Federal financial assistance in any state as defined in 29 U.S.C. § 704(14); and

4. Plaintiffs should be awarded the costs of this action, including attorney's fees, and such other relief as may be just and equitable under the circumstances.

Respectfully submitted,

/s/ Ben W. Heineman, Jr.
BENJAMIN W. HEINEMAN, JR.
VINCENT F. PRADA
1722 Eye Street, N.W.
Washington, D.C. 20006
(202) 429-4000

/s/ Jack R. Biereg
NEWTON M. MINOW
JACK R. BIEREG
JAMES C. DECHENE
One First National Plaza
Chicago, Illinois 60603
(312) 853-7000

/s/ Steven M. Bierman
STEVEN M. BIERMAN
520 Madison Avenue
New York, New York 10022
(212) 418-2100

SIDLEY & AUSTIN

RICHARD A. NOFFKE
B. J. ANDERSON
American Medical Association
535 N. Dearborn Street
Chicago, Illinois 60610
(312) 751-6000

STUART M. GERSON
Epstein Becker Borsody & Green, P.C.
1140 19th Street, N.W.
Suite 900
Washington, D.C. 20036
(202) 861-0900

MARK D. MORRIS
Hospital Association of New York State
15 Computer Drive West
Albany, New York 12205
(518) 458-7940

ANN E. ALLEN
American College of Obstetricians and Gynecologists
600 Maryland Avenue, S.W.
Suite 300-East
Washington, D.C. 20024
(202) 638-5577

JOSEPH A. KEYES, JR.
Association of American Medical Colleges
One Dupont Circle, N.W.
Washington, D.C. 20036
(202) 828-0510

MICHAEL MILLER
American Academy of Family Physicians
1740 West 92d Street
Kansas City, Missouri 64114
(816) 333-9700

Attorneys for Plaintiffs

Dated: MARCH 12, 1984

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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83 Civ. 2638 (CLB)

AMERICAN HOSPITAL ASSOCIATION
ON BEHALF OF ITS MEMBER HOSPITALS,

HOSPITAL ASSOCIATION OF NEW YORK STATE,
ON BEHALF OF ITS MEMBER HOSPITALS,

AND

STRONG MEMORIAL HOSPITAL OF THE
UNIVERSITY OF ROCHESTER, PLAINTIFFS,

v.

MARGARET M. HECKLER, SECRETARY,
UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES,
DEFENDANT.

AMENDED COMPLAINT

Pursuant to Rule 15(a) of the Federal Rules of Civil Procedure, the plaintiffs amend their complaint in this action.

Jurisdiction and Venue

1. This court has subject matter jurisdiction pursuant to 26 U.S.C. §§ 1331, 2201 and 2202, and 5 U.S.C. § 706. Venue is proper in this district under 28 U.S.C. § 1319(e).

Parties

2. Plaintiff American Hospital Association ("AHA") is an association of hospitals within the United States with approximately 6,000 member hospitals, the vast majority of which are directly and immediately affected by the federal regulation at issue in this case.

3. Plaintiff Hospital Association of New York State ("HANYS") is the association of hospitals within New York State.

4. Strong Memorial Hospital of the University of Rochester is a hospital located in Rochester, New York which provides care to infants including seriously-ill infants.

5. Defendant Margaret M. Heckler is the duly appointed Secretary ("the Secretary") of the United States Department of Health and Human Services ("DHHS") and is the federal official responsible for the administration of the regulation at issue in this action.

Statement of the Case

6. On June 16, 1982, the Office of Civil Rights of the DHHS caused to be published in the Federal Register, on behalf of the Secretary, a notice which stated that DHHS regulations regarding discrimination against the handicapped in programs receiving federal financial assistance (codified at 45 C.F.R. § 84) were applicable to the medical treatment of seriously-ill infants.

7. On March 7, 1983, without first providing for comment by interested parties, and with no evidence of any problem calling for the initiation of the regulatory process, the Secretary promulgated an interim final rule, 48 Fed. Reg. 9630, which became effective on March 22, 1983. The sole purported statutory authority for the rule was Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794.

8. The interim final rule erroneously purported to interpret Section 504 by extending its reach to infants with birth defects. Thus, the Secretary asserted that "discriminatory failure to feed and care for handicapped infants in [a hospital] is prohibited by federal law." Hospitals subject to this requirement were required to post notices to this effect in conspicuous places in each delivery ward, each maternity ward, each pediatric ward, and each nursery, including each intensive care nursery. In addition, the notice was required to indicate that a toll-free hotline, available 24 hours a day, would be provided to all persons who wish to make complaints, including anonymous complaints. Moreover, the preamble to the rule made it clear that the Secretary could conduct immediate investigations and make immediate referrals to the Department of Justice for such legal action as might be deemed necessary. Such action could be taken regardless

of the wishes of an infant's parents or other legal guardians, and regardless of the views of appropriate state law enforcement agencies or courts.

9. The interim final regulation promulgated on March 7, 1983, was intended by the Secretary to be applicable to every hospital which accepts Medicare, 42 U.S.C. §§ 1395, *et seq.*, or Medicaid reimbursement, 42 U.S.C. §§ 1396, *et seq.*, or which has received Hill-Burton assistance pursuant to 42 U.S.C. §§ 291, *et seq.*

10. The vast majority of the member hospitals of the AHA and HANYS receive Medicare reimbursement. In addition, a large number of member hospitals of both receive Medicaid reimbursement. Finally, more than 3,500 hospitals have received Hill-Burton assistance between 1947 and 1974.

11. On April 6, 1983, the plaintiffs filed the original complaint in this case, seeking a judgment declaring the interim final regulation invalid and restraining or enjoining the enforcement of that regulation.

12. On April 6, 1983, this Court temporarily restrained and enjoined defendant from enforcing the interim final rule "solely to the extent it purports to require the posting of notices upon the premises of voluntary or municipal hospitals within New York State...." The Court also scheduled a hearing for April 18, 1983, on plaintiffs' application for a preliminary injunction.

13. On April 14, 1983, the United States District Court for the District of Columbia, in a parallel case, struck down the interim final rule for failing to satisfy the requirements of the Administrative Procedure Act, 5 U.S.C. §§ 551, *et seq.* (1982). *American Academy of Pediatrics* v. *Heckler*, 561 F. Supp. 395, 400-401 (D.D.C. 1983).

14. The court in *American Academy* also ordered defendant to "place an order in the Federal Register advising that said interim final rule has been declared invalid and has no further force and effect, ..." and defendant did so declare and publish on April 25, 1983. 48 Fed. Reg. 17588.

15. In view of the invalidation of the interim final rule in the District of Columbia, the hearing scheduled by this Court for April 18, 1983 was cancelled, and defendant never

has filed or served on the plaintiffs an answer to the complaint herein.

16. On July 5, 1983, defendant proposed a somewhat revised rule (48 Fed. Reg. 30846), which itself was slightly modified when, on January 12, 1984, DHHS issued its "final rules on procedures and guidelines relating to nondiscrimination on the basis of handicap in connection with health care for handicapped infants" 45 C.F.R. § 84.55 (49 Fed. Reg. 1622). The sole purported authority for both the revised and final rule, like that for the interim final rule, is Section 504 of the Rehabilitation Act, 29 U.S.C. § 794.

17. The final rule, 45 C.F.R. § 84.55, as set forth at 49 Fed. Reg. 1622, *et seq.*, provides, *inter alia*, that:

> a. hospitals shall post a notice stating that Section 504 of the Rehabilitation Act requires that "nourishment and medically beneficial treatment . . . not be withheld from handicapped infants solely on the basis of their present or anticipated mental or physical impairments" [§ 84.55(b), 49 Fed. Reg. at 1651];
>
> b. said notice shall include a telephone number which may be called to "report suspected noncompliance" and shall state that the "identity of callers will be held confidential" [*id.*];
>
> c. state child protective services agencies must implement procedures for "immediate review of reports of suspected unlawful medical neglect of handicapped infants and, where appropriate, on-site investigation of such reports," for seeking court orders "to compel the provision of necessary nourishment and medical treatment," as well as for timely notification to DHHS of such reports and the agencies' investigation thereof [§ 84.55(c)(iii), (iv) and (v), 49 Fed. Reg. at 1651];
>
> d. hospitals must grant DHHS officials "immediate access" to "pertinent records and facilities" when the responsible DHHS official considers such access "necessary to protect the life or health of a handicapped individual" [§ 84.55(a), 49 Fed. Reg. at 1652]; and
>
> e. DHHS may, without prior notice, take expedited action to affect compliance where "necessary to protect the life or health of a handicapped individual" [§ 84.55(e), 49 Fed. Reg. at 1652].

18. The final rule therefore duplicates most of the essential aspects of the initial rule that was struck down and perpetuates the undesirable effects of that initial rule.

19. DHHS' final rule, which became effective on February 13, 1984, subjects plaintiff Strong Memorial Hospital and the many other hospital members of plaintiff associations to the requirements and procedures set forth in that rule, including those requirements and procedures described in paragraph 17, *supra*.

20. On February 23, 1984, the United States Court of Appeals for the Second Circuit ruled on the issue of whether Section 504 authorized DHHS to obtain access to a hospital's medical records concerning the treatment of an infant with serious birth defects. In answering that question with a definitive "no" the Court held that "congress never intended that Section 504 of the Rehabilitation Act would apply to treatment decisions involving defective newborn infants . . ., and that DHHS lacks authority for "the type of investigation that has precipitated this lawsuit." *United States* v. *University Hospital*, No. 83-6343 (2d Cir. Feb. 23, 1984) (slip op. at 1938-39).

21. The Court of Appeals likewise found no evidence that congress, in enacting Section 504, "intended to repeal" its "consistent . . . policy against involvement of federal personnel in medical treatment decisions, . . ." *Id.*, slip op. at 1936-37. In so holding, the Court recognized that any intervention by the government with the goal of applying Section 504 to infants with birth defects would, necessarily, involve federal personnel in evaluating, influencing and altering medical treatment decisions.

Injury

22. By its own terms, the DHHS rule is final. There is no further avenue for administrative relief, and the rule creates affirmative present obligations for the member hospitals of the plaintiff associations and for plaintiff Strong Memorial Hospital.

23. This final rule is applicable nationwide and the injury suffered by plaintiff Strong Memorial Hospital is typical of the injury suffered by the other member hospitals of the plaintiff associations.

24. If the Secretary's final rule is not held invalid and its enforcement is not enjoined, the member hospitals of the plaintiff associations and plaintiff Strong Memorial Hospital will continue to be irreparably injured in that:

a. no monetary measure can be made of the extent of the injury that plaintiffs are suffering because of the unlawful rule at issue, thus leaving plaintiffs with no adequate remedy at law;

b. the clear decision of the Court of Appeals in *University Hospital* will be flouted;

c. hospitals are required to post a notice which inaccurately states that federal law imposes upon hospital staff certain legal duties and obligations with regard to medical treatment decisions involving seriously-ill infants;

d. DHHS investigations and demand for access to patient records undertaken pursuant to DHHS' regulations, and often conducted by individuals lacking adequate knowledge or training, have been, and may be expected to continue to be, disruptive of normal and important hospital activities, and heedless of the confidentiality of patient records and the prohibitions against permitting unconsented examination of patients. See affidavits of Paul M. Rosenberg and J. Alexander McMahon, submitted with plaintiffs' original complaint herein, and the affidavit of Richard L. Epstein submitted herewith.

e. for the same reasons, the on-site investigations by state child protective agencies, compelled by a federal regulation that contains no substantive or procedural standards or limitations, are likely to be equally disruptive;

f. federally mandated suits by state child protective agencies to "compel the provision of necessary nourishment and medical treatment" will generate widespread publicity and will raise doubts and fears concerning the nature and quality of care provided by hospitals named as defendants (*see, e.g.*, Rosenberg affidavit);

g. the doubts and fears engendered by such investigations and lawsuits have induced parents to withdraw their children as patients, and may be expected in the future to induce individuals to refrain from entering or remaining in subject hospitals;

h. the conduct of the government under the rule necessarily intrudes into and interferes with parental decision-making;

i. the conduct of the government under the rule necessarily interferes with the formation and communication of accurate medical judgments and is disruptive and inhibitory of the delivery of services by hospitals and physicians throughout the nation.

COUNT I

(Violation of Section 504 of the Rehabilitation Act of 1973)

25. Plaintiffs reallege the allegations of paragraphs 1-23, *supra*, which are incorporated by reference as if set forth herein in full.

26. Because the final rule at issue here finds its only source of purported authority in Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794, it has been rendered unlawful on its face by the Second Circuit's decision in *United States* v. *University Hospital*, *supra*, in that:

a. Congress did not intend that Section 504 would apply to treatment decisions involving infants with birth defects; and

b. Congress did not intend that Section 504 repeal the longstanding congressional policy against the involvement of federal personnel in medical treatment decisions, and any activity by the federal government under the banner of Section 504 necessarily would involve the federal government in such prohibited activity.

27. The final rule is also unlawful because the federal government has no authority under Section 504 to interfere with the rights of parents to choose among treatment alternatives for their children.

28. The final rule is further unlawful because its coverage is premised upon the mere receipt by hospitals of Medicare and Medicaid reimbursements, which do not constitute federal financial assistance within the congressional intendment of Section 504. *See, Grove City College* v. *Bell*, 52 U.S.L.W. 4283 (U.S. Feb. 28, 1984).

COUNT II

(Violation of the Administrative Procedure Act)

29. Plaintiffs reallege the allegations of paragraphs 1-27, *supra*, which are incorporated by reference as if set forth herein in full.

30. In view of the Second Circuit's decision in *United States* v. *University Hospital*, *supra*, and the matters set forth in paragraphs 25-27, *supra*, the final rule must, under the requirements of the Administrative Procedure Act, 5 U.S.C. § 706(2)(C), be held "unlawful and set aside " because it is "in excess of statutory jurisdiction, authority, . . . or short of statutory right."

31. The final rule also must be set aside under 5 U.S.C. § 706(2)(A) because in promulgating and implementing it, the defendant has acted arbitrarily and capriciously, abused her discretion and otherwise has violated the law.

RELIEF REQUESTED

A. Declaratory Judgment

32. The continuation of the rule in the wake of the Second Circuit's *University Hospital* decision, which clearly mandates the invalidation of the rule, presents "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy to warrant the issuance of a declaratory judgment." *Maryland Casualty Co.* v. *Pacific Co.*, 312 U.S. 270, 273 (1940); *see Super Tire Engineering Co.* v. *McCorkle*, 416 U.S. 115, 122 (1974).

33. For the foregoing reasons, this Court should enter a judgment pursuant to 28 U.S.C. § 2201 and 2202, declaring the invalidity of DHHS' final rule, granting the relief sought for by plaintiff embodied in 45 C.F.R. § 84.55, 49 Fed. Reg. 1622, *et seq.* (Jan. 12, 1984).

B. Injunctive Relief

34. As set forth in paragraphs 21-23, *supra*, which are incorporated by reference herein, plaintiffs are suffering irreparable injury of a direct and immediate nature because of the requirements and expected enforcement of the final rule.

35. In view of the Second Circuit's *University Hospital* decision, holding that DHHS has no authority under Section

504 to intervene or act in regard to the treatment of infants with birth defects, and in view of the fact that the final rule has as its only basis the purported authority of Section 504, plaintiffs have a manifestly substantial likelihood of success on the merits of this lawsuit.

36. The hardships inherent in the existence and enforcement of the final rule tip decidedly towards plaintiffs; the Secretary can suffer no cognizable hardship if the rule she seeks to enforce is unlawful.

37. Plaintiffs satisfy all requirements for the issuance of injunctive relief. *See, e.g., Standard & Poor's Corporation, Inc.* v. *Commodity Exchange, Inc.*, 683 F.2d 704, 707-708 (2d Cir. 1982).

38. For the foregoing reasons this Court should issue a preliminary and permanent injunction prohibiting the defendant from enforcing her final rule embodied in 45 C.F.R. § 84.55, 49 Fed. Reg. 1622, *et seq.* (Jan. 12, 1984), and prohibiting defendant from otherwise acting pursuant to the claimed authority of Section 504 of the Rehabilitation Act of 1973 in regard to the medical treatment of infants with birth defects.

WHEREFORE, plaintiffs pray that this Court issue the declaratory judgment and injunctive relief sought, and such other and further relief, including the costs and attorneys' fees incurred by plaintiffs in this action, as this Court deems appropriate.

Respectfully submitted,
EPSTEIN BECKER BORSODY & GREEN, P.C.

/s/ _____
JEFFREY H. BECKER
250 Park Avenue
New York, New York 10177
(212) 370-9800

/s/ _____
STUART M. GERSON
1140 Nineteenth Street, N.W.
Washington, D.C. 20036
(202) 861-0900

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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83 Civ. 2638 (CLB)

AMERICAN HOSPITAL ASSOCIATION,
ON BEHALF OF ITS MEMBER HOSPITALS,

HOSPITAL ASSOCIATION OF NEW YORK STATE,
ON BEHALF OF ITS MEMBER HOSPITALS,

AND

STRONG MEMORIAL HOSPITAL OF THE
UNIVERSITY OF ROCHESTER, PLAINTIFFS,

v.

MARGARET M. HECKLER, SECRETARY, UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
DEFENDANT.

MOTION FOR
PRELIMINARY INJUNCTION

Pursuant to Rule 65 of the Federal Rules of Civil Procedure, the plaintiffs American Hospital Association ("AHA"), Hospital Association of New York State ("HANYS"), and the Strong Memorial Hospital of the University of Rochester ("Memorial Hospital"), upon their amended complaint, and the affidavits previously filed in this action, move this honorable Court to issue a preliminary injunction suspending and restraining the operation, enforcement, or execution of the final rule of the Department of Health and Human Services pertaining to medical treatment of infants with birth defects, 45 C.F.R. § 84.55, 49 Fed. Reg. 1622, *et seq* (Jan. 12, 1984).

The grounds of this motion, as more fully set forth in the amended complaint and in the annexed exhibits and the previously-filed affidavits of J. Alexander McMahon and Paul M. Rosenberg, and in the affidavit of Richard L. Epstein, are that:

a. the final rule is invalid because, as the United States Court of Appeals for the Second Circuit has held, Section

504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794, the sole purported authority for the final rule, does not authorize governmental involvement in medical treatment decisions concerning seriously-ill infants. *United States* v. *University Hospital*, No. 83-6343 (2d Cir. Feb. 23, 1984);

b. the final rule also is unlawful under the Administrative Procedure Act, 5 U.S.C. § 706(2)(A) and (C);

c. DHHS, unless enjoined, will continue to enforce the rule;

d. the rule and its enforcement are causing and will cause immediate and irreparable injury to the plaintiffs;

e. plaintiffs have no adequate remedy at law;

f. plaintiffs have demonstrated a substantial likelihood of success on the merits; and

g. the balance of hardships decidedly shifts towards the plaintiffs.

WHEREFORE, plaintiffs respectfully submit that this Court should enter a preliminary injunction rendering unenforceable defendants' final rule embodied in 45 C.F.R. § 84.55.

Respectfully submitted,
Epstein Becker Borsody & Green, P.C.

/s/ _____

JEFFREY H. BECKER
250 Park Avenue
New York, New York 10177
(212) 370-9800

/s/ _____

STUART M. GERSON
1140 Nineteenth Street, N.W.
Washington, D.C. 20036
(202) 861-0900

Attorneys for Plaintiffs

BEST AVAILABLE COPY

APPENDIX G

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

Civil Action No. 83 Civ. 2638 CLB

AMERICAN HOSPITAL ASSOCIATION,
ON BEHALF OF ITS MEMBER HOSPITALS,
HOSPITAL ASSOCIATION OF NEW YORK STATE,
ON BEHALF OF ITS MEMBER HOSPITALS,
AND
THE STRONG MEMORIAL HOSPITAL OF THE
UNIVERSITY OF ROCHESTER,
PLAINTIFFS,
v.
MARGARET M. HECKLER, SECRETARY,
UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES, DEFENDANT.

AFFIDAVIT

City of Washington)
) :ss
District of Columbia)

Richard L. Epstein deposes and says:

1. I am Senior Vice President of the American Hospital Association ("AHA"). The membership of the AHA comprises approximately 6,000 of the nation's 7,000 hospitals. The AHA serves its member hospitals in various ways including providing information and educational materials, and conducting seminars concerning developments in techniques and procedures for enhancing quality patient care, employee safety and related health-delivery matters. The AHA also provides information to its member hospitals with regard to the promulgation and content of federal regulations and statutes applicable to the health field.

2. I have read and am familiar with the contents of the affidavits of J. Alexander McMahon and Paul M. Rosenberg, filed with the original complaint in this case. I believe that

the relevant allegations of those affidavits continue to be true in regard to the final rule concerning medical treatment of seriously-ill infants promulgated by the Department of Health and Human Services ("DHHS") on January 12, 1984. (45 C.F.R. § 84.55, 49 Fed. Reg. 1622, *et seq.*)

3. This rule is of nationwide scope and application and, in my position, I am aware of and responsible for replying to numerous inquiries and expressions of concern from AHA member hospitals regarding the rule. The AHA is concerned with present and future irreparable harm to hospitals, physicians who practice in hospitals and the parents and patients who rely on hospitals, resulting from the implementation and projected enforcement of the final rule.

4. This final rule by its terms, deals substantially with medical treatment decisions concerning seriously ill infants, including infants with life-threatening disorders. The United States Court of Appeals for the Second Circuit has held that the sole purported statutory authority for the rule (Section 504 of the Rehabilitation Act of 1973) does not authorize the government to engage in the types of conduct contemplated by the rule. The final rule is contrary to law and sound public policy and is causing and will continue to cause irreparable harm to AHA's members and other hospitals, their personnel and medical staffs, and to the parents of infants who are treated in hospitals.

5. The final rule, which became effective on a nationwide basis on February 13, 1983, requires that hospitals receiving Medicare and Medicaid reimbursement post notices stating that Section 504 prohibits the withholding of "nourishment and medically beneficial treatment . . ." from handicapped infants solely on the basis of their present or anticipated impairments" and providing a confidential 24-hour telephone line for reporting "suspected noncompliance." The final rule further requires hospitals to grant DHHS officials "immediate access" to "pertinent records and facilities" when the responsible DHHS official considers such access "necessary to protect the life or health of a handicapped individual," and authorizes DHHS to take expedited action, without prior notice, to effect compliance where "necessary to protect the life or health of a handicapped individual." The final rule also re-

quires state child protective services agencies to implement procedures for "immediate review of reports of suspected unlawful medical neglect of handicapped infants and, where appropriate, on-site investigation of such reports," for seeking court orders "to compel the provision of necessary nourishment and medical treatment," as well as for timely notification to DHHS of such reports and the agencies' investigation thereof.

6. In its essential operative elements, particularly as to the notice-posting requirement, the "hotline" and the investigative proceedings, the rule is substantially the same as the Secretary's initial rule which was held unlawful. Moreover, the final rule perpetuates the harms occasioned by the initial rule.

7. Hospitals and their staffs are now being injured by the requirement that they post notices which erroneously state that Section 504 applies to medical treatment decisions involving seriously-ill infants. By their terms and locations, these notices imply that hospital staff has a duty to initiate governmental investigations without any objective criteria for the sufficiency of care or the exercise of medical judgment having been set forth. This situation is presently, and will remain, a source of potentially-severe disruption of the mission of care of AHA members and other hospitals.

8. Physicians and parents also are presently harmed by the inhibitory effect which the rule and its expected enforcement exerts upon their deliberations regarding the care to be provided to seriously ill infants. This undermines the discharge of hospitals' responsibilities to support the exercise of informed judgment by physicians and parents.

9. Hospitals will be irreparably harmed in the future by the enforcement of the final rule. DHHS' investigations and demands for access to patient records undertaken pursuant to DHHS' prior regulations and demands have been conducted by individuals lacking adequate knowledge or training, and have been disruptive of normal and important hospital activities and heedless of the confidentiality of patient records and the prohibitions against permitting unconsented examination of patients. DHHS investigations conducted pursuant to the final rule will be equally disruptive, as will

the on-site investigations by state child protective agencies, for the same reasons.

10. Hospitals also will be irreparably harmed by suits brought by the federal government and, pursuant to DHHS directives, by state child protective agencies, to compel specific courses of treatment, regardless of medical and parental decisions, or to compel access to patient records. Moreover, such investigations, under the rule, would be conducted without stated substantive or procedural safeguards or limitations. As has been the case in the past, suits and investigations generate widespread publicity and unwarranted anxiety concerning the nature and quality of care provided by hospitals named as defendants.

11. Physicians and other medical professionals will be irreparably harmed by the final rule by its mandated governmental intrusion into the process of medical treatment.

12. The final rule also inflicts irreparable harm upon parents of seriously-ill infants and the infants themselves. The AHA is informed that because of apprehensions raised by lawsuits and investigations, parents have withdrawn their infants as patients, and that in the future parents may be expected to refrain from permitting their children to enter or remain in the subject hospitals' care.

13. Inasmuch as the final rule is applicable on a nationwide basis to all hospitals that receive Medicare and Medicaid reimbursement, the present and future irreparable harm described herein also will be nationwide in scope, unless implementation and enforcement of the final rule are enjoined.

/s/ _____
RICHARD L. EPSTEIN
Senior Vice President
American Hospital Association

Subscribed to and sworn before me this 8th day of March 1984.

/s/ _____
Notary Public

My commission expires:
1/1/89

APPENDIX J

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Civil Action No.

AMERICAN MEDICAL ASSOCIATION, ET AL., PLAINTIFFS,

v.

MARGARET M. HECKLER, DEFENDANT.

AFFIDAVIT

STATE OF NEW YORK)
) ss:
COUNTY OF NEW YORK)

PETER A. M. AULD, M.D., being first duly sworn, deposes and says:

1. I am Director of the Perinatalogy Center at New York Hospital, 525 E. 68th Street, New York, New York 10021. The Perinatalogy Center treats several hundred infants each year with medical conditions that cannot be adequately treated at other hospitals which lack our equipment and medical expertise. I also am a Professor of Pediatrics and Obstetrics and Perinatal Medicine at Cornell University Medical College. I am a practicing Neonatalogist, and a member of several medical societies, including the American Medical Association, the American Academy of Pediatrics, and the American College of Obstetrics and Gynecology.

2. My patients include infants born with severe congenital conditions and handicaps such as Down's syndrome with accompanying complications or neural tube defects such as anencephaly and spina bifida, as well as low birth weight babies. Treatment of such infants requires difficult medical/ethical judgments. In most cases, treatment decisions are clear because treatment is expected to clearly benefit the infant. In some cases, however, certain medical treatments such as surgery, respirator treatment or IV's may offer little or no hope of improving the infant's condition, but may increase the pain and suffering of the infant.

3. In my practice, I treat an average of 800 infants each year with life-threatening conditions. Despite the fact that modern medical technology has improved the outlook for many such infants, the prognosis for many of these seriously ill infants remains extremely bleak regardless of the treatment provided.

4. Medical advances in recent years have made it possible to sustain the lives of some infants with severe medical problems for a short period of time. However, the availability of such new treatment creates a serious dilemma for the parents, who have the legal responsibility to make decisions regarding consent to the use of any particular course of medical treatment. Parents look to the hospitals, the physicians, the nurses and others to provide medical judgment for making decisions in these circumstances.

5. As a physician, I have a legal and ethical role in counseling parents about options for treatment, and I am in a unique position to identify those options to parents of newborns. The ultimate decision as to whether a particular treatment with dubious therapeutic value should be commenced must be made by concerned and loving parents, after they have been fully advised as to the expected outcome of any particular course of treatment. In all cases which I have been connected with, the parents, relying on the professional judgment of physicians and the counsel of clergy, are best able to make these difficult decisions.

6. In all my cases involving seriously ill newborns, treatment requires a trusting and open relationship between the parents of the newborn and the physician. Federal intervention in the complicated and delicate relationship between parents and physicians directly impairs this sensitive relationship. The parent-physician relationship is particularly important where parents must make decisions about the treatment and care of severely ill infants—particularly those infants with life threatening disorders for which particular courses of medical treatment do not have a high likelihood of success. Decisions regarding medical treatment of such infants involve complex clinical facts, difficult moral dilemmas and necessarily imprecise judgments. Federal involvement in these issues is both inappropriate and unhelpful.

7. Despite the inappropriateness of any Federal involvement in this area, the Department of Health and Human Services published comments and regulations on January 12, 1984 at 49 Fed. Reg. 1622 entitled "Nondiscrimination on the Basis of Handicap; Procedures and Guidelines Relating to Health Care for Handicapped Infants" which injects federal involvement into the treatment of newborn infants with severe medical conditions. I have carefully reviewed those comments and regulations and have determined that they undermine the trusting parent-physician relationship needed to treat severely ill infants, and impose obligations on physicians which impair their ability to care for such infants.

8. The regulations impose two immediate duties on physicians. First, physicians are required to report to state agencies instances of suspected "medical neglect" in the care of newborn infants whenever "nourishment and medically beneficial treatment" are withheld from "handicapped infants solely on the basis of their present or anticipated mental or physical impairments." Second, physicians are required to assist in any investigations which may be conducted under these regulations, and must make confidential medical records available to investigators without the consent of the parents.

9. Unfortunately, crucial terms included in the regulations are so vague and undefined that I have no idea what my precise obligations are. "Medically beneficial treatment," for example, requires a difficult judgment which cannot be separated from the overall condition of the patient (including handicapping conditions). It is unclear what happens when my judgment differs from the judgment of the Federal government as to the proper course of treatment in such cases. This vagueness and uncertainty causes me immediate injury.

10. The existing requirement that I report to state agencies "suspected" cases of medical neglect is causing me immediate confusion and anxiety. The existence of that duty, regardless of whether I will actually need to report any cases, undercuts my ability to practice medicine. The reporting duty impinges on the confidentiality of my parent-physician relationship. Uncertainty and confusion over the meaning of important terms in the regulation causes me anx-

iety and emotional distress as to the precise nature of my duty to report. The standards of the federal regulations and of state law create a conflicting duty with regard to my duty to advise parents of the best treatments, and my duty to report "suspected" cases of medical neglect. This reporting requirement thus causes me immediate injury by imposing a vague duty which undercuts my ability to practice medicine.

11. The challenged regulations also adversely impact my practice today by threatening court involvement in "suspected" cases of neglect. The threat of court involvement affects my ability to counsel parents as to the best course of medical treatment in particular cases.

12. The regulations also cause me immediate injury because my patients and I are subject to intrusive federal investigations triggered by unverified telephone tips to a Federal "hotline" or reports to state agencies which trigger a Federal or state investigation. Such investigations can be initiated by tips from individuals who are completely unfamiliar with the facts of an individual case. As the comments to the regulations demonstrate, none of the investigations conducted by the Federal Government under Section 504 has resulted in any findings of wrongdoing. These baseless investigations, however, obtain the medical records of patients without the parents' consent, invade the confidential parent-physician relationship and violate the right of privacy of the family of the infant.

13. The ambiguity of the regulations and the potential for baseless investigations also causes immediate injury because they affect the course of treatment in individual cases. For example, I am forced to recommend over-treatment in some cases to avoid investigations as to whether failure to recommend such treatment constitutes discrimination. Such over-treatment is not in the best interests of the impaired infants—or in the best interests of infants who may be deprived of prompt treatment because limited medical resources are devoted to hopeless cases.

14. I am also injured by the present and threatened injuries to parents of severely impaired infants. Physicians have the duty to assert the rights of the parents of the medically impaired infant. That duty is especially important here be-

cause it is unrealistic to expect parents of impaired infants to have the resources or the time to challenge the unlawful intrusion of the Federal Government at the time of an investigation into the treatment of their infants. Physicians such as Neonatalogists and Pediatricians are uniquely qualified to represent the interests of parents of newborn infants with severe medical conditions.

15. Parents of infants are injured because the challenged regulations constitute a federal attempt to legislate the outcome of these difficult and complex decisions involving critically ill newborns. Such federal intervention undermines the parent-child relationship, disrupts the confidence parents have in their infants' physicians, and inappropriately seeks to resolve complex medico-ethical disputes through litigation.

16. Court litigation at the time decisions are made generally cannot improve the quality of the parents' decision. Rapid changes in the infant's condition create substantial uncertainties with respect to the likelihood of successful treatment and the consequences of unsuccessful treatment. Objective parties can legitimately disagree as to whether a particular course of treatment is in the best interest of the child.

17. In those instances where the parents refuse to consent to painful treatments of handicapped infants which would not, in my judgment, benefit the infant, I am required by the regulations to refer the matter to an appropriate state agency. My obligation to refer such cases to state agencies undermines my professional relationships with the parents of all seriously ill infants under my care. State agency investigators invade the privacy of the involved family and subject the family, hospital and staff to adverse publicity. The family may be forced to incur legal fees to justify its action to a court considering a petition to appoint a temporary guardian for the infant.

18. If an investigation is commenced, the portion of my time spent cooperating with the investigators is lost to patient care. Investigators frequently review charts which are then unavailable to medical personnel. As a result, the length of stay in the hospital of certain patients may be ex-

tended during such investigations.

19. New York Hospital is considering creation of an Infant Care Review Committee to help respond to these dilemmas. Such a committee would review decisions to withhold treatment, provide information to parents and physicians, consult with parents and physicians regarding treatment decisions, and in appropriate circumstances refer cases to state agencies. The committee also would provide a formal channel for hospital personnel and physicians to question orders in particular cases and review policies in a manner which preserves parent-physician confidences, protects the privacy of the involved families and avoids adverse publicity.

20. The new regulations directly undermine the purpose and usefulness of such Infant Care Review Committees. Rather than proceeding through the Committee, anyone can trigger a Federal investigation by simply calling the toll-free hotline. The resulting investigation undermines parent-physician confidences, invades the privacy of involved families and generates adverse publicity for both the Hospital and the involved families.

21. Throughout my medical career, I am unaware of a single case where the regulations could have improved the difficult decisions made by parents in consultation with their infant's physicians. However, I am aware of several difficult cases where I would have been forced to alter my recommendations and actions to the immediate detriment of the critically ill infant, the parents, and other critically ill infants requiring treatment. These regulations thus have an immediate and irreparable adverse impact on patient care.

FURTHER AFFIANT SAYETH NOT.

/s/ _____

Subscribed and sworn to before me this 6th day of March, 1984.

NOTARY PUBLIC
[SEAL]

APPENDIX K

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Civil Action No.

AMERICAN MEDICAL ASSOCIATION, ET AL., PLAINTIFFS,

v.

MARGARET M. HECKLER, DEFENDANT.

AFFIDAVIT

STATE OF NEW YORK)
) ss:
COUNTY OF NASSAU)

RITA GILMAN HARPER, M.D., being first duly sworn, deposes and says:

1. I am Chief, Division of Perinatal Medicine, North Shore UniversityHospital, 300 Community Drive, Manhasset, New York. I am a practicing Neonatalogist and also serve as Consultant in Perinatal Medicine at the following hospitals: Wyckoff Heights Hospital, Brooklyn, New York; Southside Hospital, Bay Shore, New York; Brookhaven Memorial Hospital, Patchogue, New York; and St. John's Episcopal Hospitals, Smithtown and Far Rockaway, New York. I am Associate Professor of Pediatrics and Obstetrics and Gynecology at Cornell University Medical College. I am a member of the American Medical Association, the American Pediatric Society, and a Fellow of the American Academy of Pediatrics. I currently am Chairman, Committee on Fetus and Newborn, Chapter 2, District II of the American Academy of Pediatrics. I have published numerous articles relating to the care of infants born with severe medical conditions.

2. My patients include infants born with severe congenital conditions and handicaps such as Down's syndrome with accompanying complications or neural tube defects such as anencephaly and spina bifida, as well as low birth weight babies. Treatment of such infants requires an extensive medical background as well as difficult medical/ethical judgments. In most cases, treatment decisions are expected to benefit

the infant. In some cases, however, certain medical treatments such as surgery, respiratory treatment or IV's may offer little or no hope of completely correcting the infant's condition and are therefore directed toward supporting the infant's life functions. Indeed, at times, certain commonly administered therapies such as oral feedings will actually worsen an infant's condition and therefore, it is in the infant's best interest to forego oral feedings.

3. Medical advances in recent years have made it possible to sustain the lives of some infants with severe medical problems for a short period of time. It is through these attempts that in the long run, progress is made in developing new modalities for the treatment of infants and young children. For example, when I was in my first year of medical school, 95% of infants who weighed two pounds at birth died within the first twenty-eight days of life and 5% survived; now 95% survive and 5% die in the same time period. These data show that perinatal mortality has been significantly reduced in the last ten to fifteen years largely because Neonatologists have dedicated their lives to improving the medical care of critically ill infants. Advances in medicine are such that what is not feasible today will become feasible in the near future through advances in medical knowledge and therapy. There remain cases, however, where, no matter how hard the Neonatologist tries, the infant cannot be saved. For example, under our current knowledge of physiology and available treatment modalities, we are not able to save an infant with a birth weight of 350 grams.

4. The availability of new treatments creates a serious dilemma for the parents, who have the legal responsibility to make decisions regarding consent to the use of any particular course of medical treatment. Parents look to the hospitals, the physicians, the nurses and others to provide necessary knowledge and medical background for making these decisions. The ultimate decision as to whether a particular treatment should be commenced must be made by concerned and loving parents, after they have been fully advised as to the expected outcome of any particular course of treatment. In all cases which I have been connected with, the parents,

relying on the physician's experience and expertise and the advice of clergy, are able to make these difficult decisions.

5. As a physician, I have a legal and ethical role in counseling parents about options for treatment, and my twenty years as the Neonatalogist in charge of a neonatal intensive care unit give me the basis to identify those options to parents of newborns. These difficult treatment decisions are best resolved by parents and physicians.

6. Despite the fact that these decisions are best resolved by parents and physicians, the Federal Government recently has sought to control these decisions. The most recent mechanism for injecting Federal control is described in the comments and regulations published by the Department of Health and Human Services on January 12, 1984 at 49 Fed. Reg. 1622 entitled "Nondiscrimination on the Basis of Handicap; Procedures and Guidelines Relating to Health Care for Handicapped Infants." I have reviewed those comments and regulations and determined that they will in no way increase the quality of care for infants with severe medical problems. Indeed, the regulations impose new requirements on Neonatologists and other physicians which will reduce their availability for the care of infants.

7. Those regulations impose two immediate duties on physicians. First, physicians are required to report to state agencies instances of suspected "medical neglect" in the care of newborn infants whenever "nourishment and medically beneficial treatment" are withheld from "handicapped infants solely on the basis of their present or anticipated mental or physical impairments." Second, physicians are required to assist in any investigations which may be conducted under these regulations, including making confidential medical records available to investigators.

8. Unfortunately, crucial terms included in the regulations are so vague and undefined that I have no idea what my precise obligations are under the regulations. For example, as part of the best standard of medical care, oral nourishment is routinely withheld from some infants with gastrointestinal malformations, infections, respiratory distress and other entities whether or not the infant has present or anticipated mental or physical impairments. Should these be reported?

What might be considered medical neglect by one physician would be considered adequate therapy by another. Moreover, I routinely administer therapies to infants which I consider will be beneficial to the infant. Any obligation to refer cases of "suspected medical neglect" where someone could claim that I was withholding beneficial treatment is incongruous with the way I practice medicine daily.

9. The requirements that I report to state agencies "suspected" cases of medical neglect undercuts my ability to practice medicine. In all cases involving seriously ill newborns, treatment requires an extensive dialogue and a trusting and open relationship between the parents of the newborn and the physician. The regulations directly impair this sensitive relationship by implying that the physician has not disclosed the facts adequately and that there is a physician somewhere with superior knowledge and ability. Decisions regarding medical treatment of such infants involve complex clinical expertise, difficult moral dilemmas and necessarily imprecise judgments. Federal involvement in these issues is both inappropriate and unhelpful.

10. These regulations also impede the advancement of medicine. Neonatologists will not be able to develop new treatments and methods of care for infants with severe medical complications while the Federal Government is looking over their shoulders. Fear of the consequences of unsuccessful attempts will thwart the efforts which are essential for progress in the treatment of infants.

11. Many hospitals, including North Shore University Hospital, have responded to the dilemmas posed by these cases by establishing Infant Care Review Committees. These committees review decisions to withhold treatment, provide information to parents and physicians, consult with parents and physicians regarding treatment decisions, and in appropriate circumstances refer cases to state agencies. These committees also provide a formal channel for hospital personnel and physicians to question orders in particular cases and review policies in a manner which preserves parent-physician confidences, protects the privacy of the involved families and avoids adverse publicity.

12. The new regulations directly undermine the ability of the Infant Care Review Committee to assist in these matters. Rather than proceeding through the Committee, anyone can trigger a Federal investigation by simply calling the toll-free hotlines. Such a course undermines the Committee, destroys the parent-physician relationship, invades the privacy of involved families and generates adverse publicity for the involved families.

13. Objective parties can legitimately disagree as to whether a particular course of treatment is in the best interest of the infant. The optimal treatment in any given case is a function of the available equipment, the physician's knowledge of the disease and treatment modalities, and of crucial importance, the physician's ability to practice the "art" of medicine. The challenged regulations adversely impact upon my practice today by threatening court involvement in "suspected" cases of neglect where someone else's detached hindsight substitutes for the judgments I make during the course of therapy. The regulations also immediately affect me by infringing upon my right to practice medicine according to my professional judgment and medical ethics.

14. As a physician, it is my duty to assert the legal rights of my patients and their families. Physicians must raise these rights because parents in an individual case will not have the time or resources to defend their rights. Moreover, the challenged regulations directly affect me as a physician by interfering with the confidential patient-physician relationship. The threat of governmental involvement reviewing my treatment decisions affects my ability to counsel parents as to the best course of medical therapy.

15. Investigations triggered by these regulations invade the privacy of the involved family and subject the family, hospital and staff to adverse publicity. The family may be forced to incur legal fees to justify its action to a court considering a petition to appoint a temporary guardian for the infant. If an investigation is commenced, the portion of my time spent cooperating with the investigators is lost to patient care. This may be the very critical time needed by the infant. As a result, quality of care may be severely jeopardized.

16. The challenged regulations constitute a Federal attempt to legislate the outcome of the difficult and complex decisions involving critically ill newborns. Such Federal intervention undermines the parent-child relationship, disrupts the confidence of parents in their physicians, and inappropriately seeks to resolve complex medico-ethical disputes through litigation.

17. Throughout my medical career, I am unaware of a single case where the regulations could have improved the difficult decision made by parents in consultation with their infant's physicians. However, I am aware that a "Big Brother" overseer in the nursery will inhibit application of new therapies for the care of infants, will interfere with critical care support systems offered to infants, will destroy the parent-physician relationship, and will foster the development of a new bureaucracy. The money spent in administering these regulations would offer much greater benefit if devoted to perinatal research. These regulations have an immediate and irreparable adverse impact on the care of the newborn.

FURTHER AFFIANT SAYETH NOT.

/s/ _____

Subscribed and sworn to before me this 7 day of March, 1984.

/s/
Notary Public
[SEAL]

APPENDIX N

AFFIDAVIT

Paul M. Rosenberg, having been duly cautioned and sworn, hereby states that:

1) He resides at 12 Pickford Drive, Rochester, New York, and is employed by Strong Memorial Hospital of the University of Rochester, Rochester, New York, as Associate Director, Fiscal and Administrative Services. Responsibilities of this position include the legal affairs of the Hospital, and entail contact with the representatives of regulatory and investigative agencies. Additionally, affiant takes administrative call for the Hospital on a scheduled basis, responding to unusual situations.

2) The Hospital is in compliance with the requirements for posting notice of the "Infant Doe Hotline" number and other information as required by 45 CFR Part 84, § 84.61, Amended.

3) During the week of March 28, 1983, he was assigned to take administrative call for the Hospital, and that on March 29, 1983, at approximately noon, he received a call from an individual identifying himself as Alan Brotman, Investigator, Office for Civil Rights, Department for Health and Human Services, New York Regional Office.

4) Mr. Brotman advised him that a Washington hotline call had been received by his agency, reporting that conjoined (siamese) twins were admitted to Strong Memorial Hospital and that said twins might be denied nutrition or treatment, and that said report triggered a duty on the part of Mr. Brotman to conduct an investigation, which would begin that afternoon. When asked the nature of said hotline report, Mr. Brotman indicated that a caller from Binghamton, New York had read of the twins' admission in a local newspaper, that the newspaper account indicated that said twins might not survive, and that the caller provided no information beyond that contained in the newspaper account. Mr. Brotman could not provide details, and contact with the Washington Office produced a promise to provide the time of call, name of person who received the call, and a transcript or summary of the facts reported or allegations made by the caller. Mr.

Brotman proceeded to ask preliminary medical questions about said patients. After verifying Mr. Brotman's identity with his supervisor, Mr. David Coronado, affiant answered those questions to the best of his ability. Mr. Brotman then left his office to make travel arrangements to Rochester.

5) Mr. Coronado, in a separate telephone conversation, assured affiant that Mr. Brotman would bring a written request for information in this matter, along with a written statement of his authority. During this conversation, Mr. Coronado also advised that a second investigator, Ms. Zulma Soto, would accompany Mr. Brotman.

6) Affiant then set about obtaining certain information which had been requested for review by Mr. Brotman including a copy of medical records, with patient identification information deleted, and certain Hospital policy information. He also arranged to make the patient's attending physician available for interview by the investigators.

7) Prior to the arrival of Mr. Brotman and Ms. Soto, affiant was again contacted by Mr. Coronado, who advised that an investigator from his agency's Washington, D.C. headquarters, Carole L. Brown, would be joining the New York investigators.

8) Ms. Brown arrived at Strong Memorial Hospital at approximately 4:00 PM and that investigators Brotman and Soto arrived at approximately 4:30 PM, and that none of them delivered any written request for information, verification that a phone call had been actually made to the Washington hotline, or written statement of investigative authority. The investigators presented their investigative identification materials only.

9) After review of investigative credentials, affiant provided the aforementioned medical records copy for review by the investigators and answered their questions. The investigators then disagreed among themselves as to which of their offices was entitled to the copy of the medical records. The patients' attending physician was then made available for a lengthy interview about the patients' condition, care, decision-making, involvement of the family in decision-making, and other items of confidential information.

10) While said interview took place, the investigators were advised by telephone that a neonatologist would be sent to Rochester that evening to assist with their investigation. After some confusion, the neonatologist was identified as Dr. Frederick Wirth of Norfolk, Virginia. Requests for interviews with other staff members were denied by affiant, and it was agreed that further inquiry would await arrival of Dr. Wirth.

11) Upon learning that a physician was being dispatched, and upon the presumption that he would request to examine the patients, and upon learning that a report of the investigation being conducted by the federal agency was being carried on local news media, affiant advised the attending physician to contact the patients' parents and solicit their views on further cooperation with the investigation, and particularly, as to whether they would authorize an examination of the patients by Dr. Wirth.

12) Dr. Wirth arrived in the Rochester area, conferred with the investigative team, and telephoned the affiant at approximately 10:00 PM to advise that he wished to examine the infants and review the medical records.

13) Affiant advised Dr. Wirth that the Hospital would not authorize such examination without consent of the patients' parents, and that Dr. Wirth stated that he was surprised that no authorization had been obtained, as he had believed that the investigative team would obtain written authorization for examination by the physician investigator. Dr. Wirth stated that he had discussed the case with the investigators based on their notes and recollections from the afternoon's record review and interviews, and that based on that discussion he was fully supportive of the medical decision-making, level of parental involvement in said decision-making, and overall patient management in the case.

14) The attending physician conferred further with the patients' parents at 8:00 AM on March 30, and was advised that the parents opposed examination of the patient by a physician member of the investigative team. This refusal was communicated to Dr. Wirth by affiant, and also to Carol Brown. Dr. Wirth advised that he would not be involved further in the case. Ms. Brown advised that the team had been

instructed to return to its respective offices in the event there was a refusal of further cooperation with the investigation.

15) No written communication regarding the request for information, the nature and scope of the investigation, or verification that a hotline report was actually made has been received by Strong Memorial Hospital. Despite direct telephone inquiry by the affiant to Mr. Brotman and Ms. Brown, the agency has been unable to advise affiant and the Hospital as to which office will be responsible for completing the investigation, preparing a report, and closing the investigative file.

16) Despite an informal verbal assurance to the affiant that all was found to be in order by the investigating team, and that no violation of any federal regulation would be found, the investigative agency can give no prediction of when it will be prepared to make public statements or a statement to the patients' family to that effect, countering the traumatic effect of this invasion of the family's privacy and of numerous newspaper accounts of the investigation which appeared in the Rochester region. The confusing and disorganized approach taken by the Agency in investigating and following up this complaint has compromised the Hospital's ability to assist the family of infants born with profound congenital malformations in formulating an appropriate care plan, due to the fact that the family now feels that any decisions it makes will be subject to similar scrutiny. The harm caused by the Agency's loose and ill-defined investigative and administrative procedures extends beyond this one tragically affected family. Parents of other critically ill children have questioned whether the Hospital is intentionally harming children, and on April 1, one family withdrew a seriously ill patient from the Hospital before completion of treatment due to fears that the Hospital was intentionally harming children, caused by their reading of local newspaper accounts of the investigation.

On April 1, 1983, Paul M. Rosenberg appeared personally before me, a Notary Public licensed in the State of New York, and swore that the above was his own truthful statement, and signed in my presence.

/s/ _____ /s/ _____

Notary Public PAUL M. ROSENBERG

APPENDIX O

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 83-0774

AMERICAN ACADEMY OF PEDIATRICS; NATIONAL ASSOCIATION OF CHILDREN'S HOSPITALS AND RELATED INSTITUTIONS, INC.; AND CHILDRENS HOSPITAL NATIONAL MEDICAL CENTER, PLAINTIFFS,

v.

MARGARET M. HECKLER, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DEFENDANT.

AFFIDAVIT OF NORMAN B. URMY

I, Norman B. Urmy, being first duly sworn makes oath as follows:

1. I am Director of the Vanderbilt University Hospital and have held this position since August of 1982. I am providing this affidavit at the request of the National Association of Childrens' Hospitals for use in its lawsuit against the Department of Health & Human Services ("HHS"). The purpose of this affidavit is to describe a site investigation by the Office of Civil Rights ("OCR") of HHS on March 23 and 24, 1983 in response to an anonymous call to the hotline established by HHS. This affidavit is based on my personal knowledge and on information given me by Dr. David Karzon, Chief of Pediatrics, Ms. Sharon Cox, Associate Director of Nursing for Children's Hospital and other members of the Hospital staff.

2. In the early afternoon of Wednesday, March 23, Vanderbilt University Hospital was called by Ms. Mildred Wise of OCR's Atlanta Regional Office. Ms. Wise said that an individual had used the hotline to report that Vanderbilt University Hospital was not providing proper medical treatment or proper nourishment to ten named children at the

Hospital. Ms. Wise asked for information concerning the current medical status, diagnosis and prognosis of each of these ten children and requested that the information be provided within one hour. We informed her that we would give OCR the information but that it could not be done within one hour. Ms. Wise stated that federal investigators planned to catch the next available flight to Nashville and would like to meet with Hospital officials and physicians at 9:30 p.m., the night of March 23.

3. We were informed that the site inspection team would consist of two investigators from OCR Atlanta, one investigator from OCR Washington and a physician/consultant, Dr. William Keenan, a neonatologist with the Cardinal Glennon Children's Hospital in St. Louis, Missouri.

4. On the afternoon of March 23, Ms. Cox reviewed the files of the ten patients and, based on her report, we concluded that there was no medical basis for the call, since all ten patients were receiving complete, aggressive and excellent medical care. In particular, all ten patients were receiving nourishment.

5. We contacted the attending physicians for each of the ten children, explained the situation to them, and invited them to the initial meeting with the OCR investigators. The meeting, which I attended for most of the time, began at 9:30 p.m. and continued until approximately 11:45 p.m. The attending physicians and the Chief Pediatric Resident (to the extent that the attending physician could not attend) discussed the medical history, course of treatment, nourishment and prognosis of each of the ten children utilizing the medical record.

6. After the meeting, Dr. Karzon and the Chief Pediatric Resident, and Dr. Keenan, the OCR physician/consultant, made "rounds" to visit each of the patients.

7. On the following day, March 24, the OCR team arrived at the Hospital at approximately 8:00 a.m. and stayed until 4:00 p.m. Hospital records of the ten children were made available to them for their review in detail. The investigators had indicated they wanted to personally review the medical records in order to verify the information provided to them verbally the night before by the attending physi-

cians and Chief Pediatric Resident. The investigators also interviewed nursing staff (supervisory and other primary care nurses), Hospital administration, and the Chief of Pediatrics.

8. On March 24, we asked the OCR team for a preliminary report as to their findings. (A similar request was also made at the meeting the night before.) The OCR team refused and said that we would have to await their final report, which would be issued within the next thirty to ninety days. The OCR team, however, expressed no concern about any of the ten patients and certainly took no action to "protect" any of them.

9. Dr. Keenan, the OCR physician/consultant, made the following statement to us: "The care of the ten children at Vanderbilt University Hospital is exemplary, supportive both biologically and psychologically in all respects." Dr. Keenan emphasized that these were his personal medical opinions and that they did not necessarily reflect what would appear in the final official report to be issued by OCR.

10. Although the OCR team conducted themselves in a professional manner and Vanderbilt attempted to cooperate with them, the investigation was time consuming, disruptive and indirectly expensive. Dr. Karzon worked eight hours with the OCR team; Ms. Cox worked eighteen hours assisting them. The Chief Pediatric Resident spent ten hours assisting the OCR team. Six nurses on our staff were interviewed by the OCR team for a total of three hours. These doctors and nurses would have otherwise spent their time caring for patients.

11. Most importantly, however, the OCR investigation had adverse effects on medical care given the ten patients involved.

(1) One patient remained in the Pediatric Intensive Care Unit longer than necessary because his chart was unavailable for the housestaff to review and write discharge orders.

(2) On March 24, the housestaff were unable to review laboratory reports and update orders following rounds since the charts were in the possession of the OCR team. Copies of laboratory reports had to be ordered and numerous calls were required to the laboratory to obtain information.

(3) There were delays in the transporting of patients from the Pediatric Intensive Care Unit to the Operating Room since charts had to be retrieved from the investigators.

(4) Six nurses were pulled from patient assignments for interviews with the OCR team. Several of these interviews occurred during changes of shifts, which delayed reports on patients to the nurses on the next shift.

For these reasons, there was disruption of Hospital activities and patient care, and patient safety was placed in potential jeopardy by the OCR investigation.

FURTHER AFFIANT SAITH NOT.

I declare under penalty of perjury under the laws of the United States that the foregoing statements are true and correct.

DATED this 5th day of April, 1983.

/S/ Norman B. Urmy
NORMAN B. URMY

STATE OF TENNESSEE)

COUNTY OF DAVIDSON)

Sworn to and subscribed before me this 5th day of April, 1983.

/S/ John C. Cellison
JOHN C. CELLISON
Notary Public

My Commission Expires: July 27, 1986.

Excerpts from:

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Deciding to Forego Life-Sustaining Treatment*

Chapter 6, "Seriously Ill Newborns," pages 223-229.

Policy Evaluation and Recommendations

The few systematic studies of decisionmaking about seriously ill newborns support the contentions of care professionals before the Commission and elsewhere that such decisionmaking usually adheres to the precepts outlined in this chapter.[90] As shown previously, however, problems of two kinds do occur: (1) parents receive outdated or incomplete information from their physicians and this limits their capacity to act as surrogate decisionmakers,[91] and (2) in what appears to be a limited number of cases, inappropriate decisions are made without triggering a careful reevaluation.[92]

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[90] *See* notes 46-49 *supra*.

[91] Hein, *supra* note 74.

> When they [parents] begin to hear both points of view—sometimes it's only that there are excellent adoptive homes for such kids—that's often never raised—that changes the decision. Sometimes they just need to learn more about Down's. Parents have such horrible fantasies about it; it's mongolism and it's something monstrous, they think. This wider process is often nothing more exotic than bringing facts into the discussion.

Testimony of Dr. Norman Fost, transcript of 16th meeting of the President's Commission (Jan. 9, 1982) at 161.

[92] Robertson, *supra* note 76. Perhaps the best-known case, and the only one in which there is an appellate court decision, is the one that has come to be known as the Infant Doe case, in which parents elected to forego treatment of their newborn child who had Down syndrome, tracheoesophageal atresia, and possibly additional anomalies. The course of nontreatment was one "medically recommended" way in which to proceed, according to the opinion of the trial court in an action brought by child welfare authorities on the complaint of some party other than either the physicians or the parents of the child. The trial court eventually sustained the parents' decision not to treat. *In re* Infant Doe, No. GU 8204-00 (Cir. Ct. Monroe County, Ind. April 12, 1982), *writ of mandamus dismissed sub nom.* State *ex rel.* Infant Doe v. Baker, No. 482 S

Improving Initial Decisions. The Commission believes that professional associations and health care institutions should help ensure that the best information is available and is used when decisions about life-sustaining treatment are made.[93] This is especially important in the cases of neonates because of both rapidly expanding medical capabilities and other efforts to maximize the potential of the disabled. Physicians should seek, and institutions might require, specialist consultations in such cases.

Where problems arise in communication between parents and nurses or physicians, institutions should provide responsive means to improve the communication and resolve the impasse. A high priority for care givers in this area should be the development of personal and team skills in communication and the enhancement of surrogates' capacities for effective decisionmaking.

Ensuring Appropriate Review. Although personal morality and compassion, high standards of professional ethics, and current laws and regulations ensure that the vast majority of decisions about seriously ill infants are made correctly and that incorrect decisions are redressed, occasionally actions are taken without the consent of an infant's surrogate or tragically erroneous decisions are made by both physicians and surrogates. Judicial proceedings provide a possible means to handle these situations, although the Commission does not find them to be the best—nor even a very available and convenient—method.

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140 (Indiana Supreme Ct., May 27, 1982) (case mooted by child's death). Assessing this case is made difficult by the privacy concerns involved in judicial proceedings. *See* Steven R. Valentine, *Briefs Ordered Sealed in "Infant Doe" Appeal Case*, RIGHT TO LIFE NEWS, Nov. 24, 1982, at 8.

[93] You were asking if it is possible to do it [counsel parents of seriously ill newborns] without a team.... I can't imagine doing it without a team, frankly, because there are so many different parts of each parent that need attending to in a decision that is the most excruciating one they will ever make, and no one professional discipline can do all of that.

Testimony of Carol Kennon, Social Worker, transcript of 16th meeting of the President's Commission (Jan. 9, 1982) at 31. *See also* Hein, *supra* note 74.

Actions taken without a surrogate's consent are not readily susceptible to redress through the courts, since the parents are not likely to be in a position to evaluate—or even to detect—what is happening in their child's care if they are excluded from decisionmaking; furthermore, civil proceedings would be cumbersome, costly, and slow.[94] In many institutions, people concerned about erroneous decisions by both physicians and surrogates intervene only by complaining to public officials that child abuse or criminal homicide has occurred or may be about to occur. This very serious accusation usually requires that the complainant believes the evidence is sufficient to warrant legal action.

Furthermore, the adversarial atmosphere generated by this approach is unlikely to lead to infants receiving the most suitable care. The same problem arises with the regulations issued by the Department of Health and Human Services in

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[94] I think we have . . . a real contrast in time-frame analysis between the medical and legal profession. . . . When we talk about quick court decisions we are talking about 12 days. When I talk about quick, it means running down the stairs rather than taking an elevator. . . . You have to understand when physicians want an answer they want it in 10 minutes. When lawyers produce an answer, they congratulate themselves for producing it in 10 days.

Testimony of Dr. Marianne Prout, transcript of 10th meeting of the President's Commission (June 4, 1981) at 35-36; Arnold Relman, *The Saikewicz Decision: A Medical Viewpoint*, 4 L. & MED. 233 (1978).

In addition to being ill-equipped to respond quickly enough to life-threatening situations, courts have been criticized for being unable to respond to the dynamic nature of decisionmaking necessary for medical treatment choices. *Compare* the statement of I. David Todres in Cynthia B. Wong and Judith P. Swazey, eds., DILEMMAS OF DYING: POLICIES AND PROCEDURES FOR DECISIONS NOT TO TREAT, G.K. Hall Med. Pub., Boston (1981) at 122-23 *with* Maine Medical Center v. Houle No. 74-145 (Super. Ct. Cumberland County, Me., Feb. 14, 1974) *reprinted in* Robert F. Weir, ed., ETHICAL ISSUES IN DEATH AND DYING, Columbia Univ. Press, New York (1977) at 185. *In re* Teague, No. 104-212-81886 (Cir. Ct. Baltimore, Md., filed Dec. 4, 1974) (child born with spina bifida died before action could be taken on the case.). *See* p. 159 *supra*.

the wake of the *Infant Doe* case[95] to prevent handicapped infants from being "discriminatorily denied food or other medical care."[96] Instead of adding further uncertainty to an already complex situation,[97] the Federal government would do

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[95] Office of the Secretary, Department of Health and Human Services, *Nondiscrimination on the Basis of Handicap*, 48 Federal Register 9630 (1983) (interim final rule modifying 45 C.F.R. § 84.61). *See also* Office for Civil Rights, Department of Health and Human Services, *Discrimination Against the Handicapped by Withholding Treatment or Nourishment; Notice to Health Care Providers*, 47 Federal Register 26,017 (1982) (notice issued May 18, 1982, applying 45 C.F.R. Part 84 to health services for handicapped children), *reprinted in* Appendix H, pp. 467-68 *infra*.

Under the March 1983 notice, a warning must be posted in relevant places in hospitals that it is unlawful to exclude any "otherwise qualified handicapped individual" from the benefits of any Federally assisted program. A toll-free 24-hour "hotline" number is provided for anyone who knows of any handicapped infant who is being denied food or "customary medical care." Under the earlier notice, the Department reminded the nearly 7000 hospitals that receive Federal aid that existing HHS regulations apply § 504 of the Rehabilitation Act of 1973 to health services and treat Down Syndrome as a handicap within the meaning of § 504. Prior to 1982, § 504 had only been used once in the context of newborns with congenital anomalies. *See* Protection and Advocacy Agency of Hawaii v. Kapiolani Children's Hospital, Health and Human Services Doc. No. 09-79-3158 (1980), *cited in* Nancy Lee Jones, *Application of Section 504 of the Rehabilitation Act of 1973 to Handicapped Infants*, Congressional Research Service, Library of Congress, Washington (July 9, 1982).

[96] *Discrimination Against the Handicapped*, *supra* note 95, at 9630.

[97] Questions remain, for example, concerning such difficult matters as decisions regarding very low birth weight babies on the edge of viability, decisions for those with multiple serious congenital anomalies, and decisions for infants who are dying. Witnesses testifying before the Commission expressed concern that virtually every operative phrase of the DHHS directive needs amplification and would be subject to varieties of interpretation.

> There are two problems with Section 504: (1) it is not clear if or why a handicap can *never* be a justification for withholding treatment; and (2) the phrase "medically contraindicated" is ambiguous . . . the wording of this exemption is so vague that it is unintelligible. What is meant by a medical contraindication to treatment?. . . . The language of Section 504 does not tell us *whether* it is permissible to withhold dialysis from a hydranencephalic child, or *why* it is impermissible to withhold intestinal surgery from a child with Down Syndrome.

Norman Fost, *Putting Hospitals on Notice*, 21 HASTINGS CTR. REP. 5 (Aug. 1982). *See also, Life Support Notice Attacked*, AM. MED. NEWS,

better to encourage hospitals to improve their procedures for overseeing life-and-death decisons, especially regarding seriously ill newborns. Using financial sanctions against institutions to punish an "incorrect" decision in particular cases is likely to be ineffective and to lead to excessively detailed regulations that would involve government reimbursement officials in bedside decisionmaking. Furthermore, imposing such sanctions could unjustly penalize the hospital's other patients and professionals.

The Commission concludes that hospitals that care for seriously ill newborns should have explicit policies on decisionmaking procedures in cases involving life-sustaining treatment for these infants; accrediting bodies could appropriately require this. Such policies should provide for internal review whenever parents and the attending physician decide that life-sustaining therapy should be foregone. Other cases, such as when the physician and parents disagree, might well also be reviewed. The policy should allow for different types of review and be flexible enough to deal appropriately with the range of cases that could arise. Some cases may require only a medical consultation to confirm a diagnosis of an inevitably fatal condition, for example. In other cases, when the benefits of therapy are less clear, an "ethics committee" or similar body might be designated to review the decisionmaking process.[98] This approach would ensure that an individual or group whose function is to promote good decisionmaking reviews the most difficult cases. Cases included in this category should certainly encompass those in which a decision to forego life-sustaining therapy has been proposed because of a physical or mental handicap, as well as cases where a dispute has arisen among care givers and surrogates over the proper course of treatment.

Such a review could serve several functions and the review mechanism may vary accordingly. First, it can verify

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July 16, 1982 at 17 (response by American Academy of Pediatrics to the Section 504 directive).

Furthermore, the term "handicapped" is in no way limited in application to neonates. The impact of a regulation of this sort on the care of other patients could be substantially in conflict with this Report.

[98] *See* pp.160-70 *supra*.

that the best information available is being used. Second, it can confirm the propriety of a decision that providers and parents have reached or confirm that the range of discretion accorded to the parents is appropriate. Third, it can resolve disputes among those involved in a decision, by improving communication and understanding among them and, if necessary, by siding with one party or another in a dispute. Finally, it can refer cases to public agencies (child protection services, probate courts, or prosecuting attorneys) when appropriate. Such a review mechanism has the potential both to guarantee a discussion of the issues with a concerned and disinterested "representative of the public" and to insulate these agonizing, tragic decisions from the glare of publicity and the distortions of public posturing that commonly attend court proceedings.

Insofar as possible, infants' lives should be sustained long enough to gather the best information and to permit expeditious review. When the parents and physician feel justified in acting without either or both of these conditions, as might happen with a rapidly deteriorating medical status, retrospective review should be undertaken.[99] Unlike turning to the courts for scrutiny of every case involving treatment of a seriously ill newborn, review of this limited category of cases would not seem likely to generate inappropriate social or financial costs.

In light of the lack of comprehensive information about decisionmaking practices and the fact that the Commission's recommendation is largely untried, the Commission encourages institutions, social scientists, and funding agencies to evaluate the effectiveness of such regularized review in order to improve its efficiency and efficacy and to refine the definition of the circumstances in which it is needed.

Long-Term Implications. The value society places on promoting the health and welfare of children has ramifica-

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[99] Ensuring a retrospective review removes any incentive for hasty actions to avoid prospective review, a course that could be a disadvantage to at least some newborns. Retrospective review cannot change what happened to a particular child, but it can help ensure a high standard of decisionmaking practices in the institution and can censure seriously erroneous decisionmaking, both internally and by referral to the courts.

tions beyond neonatal intensive care units. When the decision is made to give seriously ill newborns life-sustaining treatment, an obligation is created to provide the continuing care that makes a reasonable range of life choices possible. A major conference on critically ill newborns concluded:

> The advocates of intensive care must become the advocates for development of humane continuing care and for sufficient funding of programs to support families whose children require special attention at home or in institutions. Neonatology cannot be developed in isolation from the continuing specialized care which, unfortunately, will be needed by some of the survivors of life-threatening neonatal disorders.[100]

Adoption and foster care should be available for parents unable to raise their seriously handicapped child.[101] To aid parents, support that is responsive to the emotional and financial demands of handicapped persons and their families should be available. As a physician who has been pioneer in the treatment of infants and children recently commented, such support is an essential concomitant to a commitment to sustaining life.

> I'm very much involved in making sure that habilitation and rehabilitation of spina bifida individuals is advancing, because that's really the hope. If . . . I have preserved a thousand children who are going to sit in wheelchairs in nursing homes with normal intelligence

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[100] Albert R. Jonsen *et al.*, *Critical Issues in Newborn Intensive Care: A Conference Report and a Policy Proposal*, 55 PEDIATRICS 756, 764 (1975).

[101] As long as the state offers institutions that provide little more than storage space and "hay, oats, and water" for medical science's achievements, the law must err on the side of its strong presumption in favor of parental autonomy and family integrity. Thus for the state to do other than *either assume* full responsibility for the treatment, care, and nurture of such children *or honor* the parent's decision to consent to or refuse authorization for treatment would be but to pay cruel and oppressive lip service to notions of human dignity and the right to life.

Joseph Goldstein, *Medical Care for the Child at Risk: On State Supervision for the Child at Risk*, in Gaylin and Macklin, *supra* note 66, at 153.

> .... if that's what I've done, I've created a nightmare.[102]

Private organizations have made enormous contributions on behalf of the disabled; yet public funds may ultimately be needed so that these children, once rescued, are not then left to drown in a sea of indifference and unresponsiveness. Public support for effective voluntary organizations and governmental programs is the inescapable extension of society's deep interest in sustaining life in neonatal intensive care units. Furthermore, to the extent that society fails to ensure that seriously ill newborns have the opportunity for an adequate level of continuing care, its moral authority to intervene on behalf of a newborn whose life is in jeopardy is compromised.

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[102] Dr. David McClone, Interview on *Sunday Morning* (transcript), CBS Network, Aug. 29, 1982, at 25.

Supreme Court of the United States

No. 84-1529

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

AMERICAN HOSPITAL ASSOCIATION, ET AL.

ORDER ALLOWING CERTIORARI. *Filed June 17, 1985.*

The petition herein for a writ of certiorari to the *United States Court of Appeals for the Second Circuit* is granted.